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~~PREScription MANAGEMENT SYSTEM~~

TECHNICAL FIELD

- 1 This invention relates to professional data management
2 systems useful in the production of product specification
3 documents such as prescriptions, service or parts orders,
4 insurance contracts and the like that require detailed
5 product and history information from multiple extensive
6 information sources, especially remote heterogenous sources.
7 More particularly, the invention relates to systems that
8 assist professionals perform their everyday work in
9 specifying customized technical products. A particularly
10 preferred embodiment relates to a computer-implemented
11 prescription management system to assist physicians in
12 prescribing and reviewing drugs.



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BACKGROUND

An important professional activity undertaken by most physicians during the course of their day is the prescribing of drugs. Many physicians prescribe a great number of drugs every day. Studies show that over two thirds of all doctor-patient encounters were completed with the writing of a prescription. In 1993 typical prescribers were prescribing in excess of two hundred thousand dollars-worth of drugs annually. While most physicians exercise the utmost of professional skill and caution in prescribing, there are inherent difficulties and uncertainties in the process. Most physicians will probably agree that they do not have access to adequate, reliable drug information and relevant patient information at the time and point of prescription. In particular, information regarding relevant new drugs, comparative efficacy, and importantly, relative costs, may not be readily and conveniently available to a physician creating a new prescription, as well as relevant patient information such as current conditions being treated, current treatments, and preferred medications for conditions, pursuant to requirements of the patient's drug formulary.

Nevertheless, while accessing it is impractical for the typical practitioner, such information is available to any physician willing to take the time and make the effort to

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1 obtain it.

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3 In contrast, integrated patient-specific information which
4 is directly relevant to treatment management for the subject
5 patient is frequently both unavailable to, and unobtainable
6 by, a prescribing physician unless that physician's
7 institution or organization has been exhaustively
8 responsible for the subject patient's prior care and
9 maintains sophisticated computerized records. Information
10 as to allergies, current prescriptions and currently active
11 conditions is clearly desirable or essential for intelligent
12 prescribing. In 1994, few prescribing sessions are
13 conducted with the benefits of integrated patient-specific
14 information and fewer still have the benefit of specific
15 drug formulary recommendations on the subject patient.

16 ~~Typically, drug formularies comprise lists of preferred~~
17 ~~drugs whose costs will be borne by a drugs benefit house.~~
18 Drug formulary information is usually determinative of the
19 cost-effectiveness of a prescription. Unwitting failure by
20 a prescriber to follow formulary guidelines can impose
21 unnecessary or unexpected cost burdens on the patient, or
22 their benefits provider, and lead to poor patient compliance
23 and aggravating and time-consuming disputes. The cost in
24 dollars of non-compliance with drug formulary guidelines to
25 benefit-providing corporations, insurers, health maintenance
26

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1 organizations and government providers, for example MEDICAID
2 and MEDICARE, can be enormous. The cost of poor patient
3 compliance may ultimately increase the total cost of care by
4 generating a more serious, expensive adverse health outcome
5 (emergency room visit, or hospital admission or death).
6

7 A difficulty in making integrated patient-specific
8 information readily available to prescribing professionals
9 is that the needed information components are not
10 centralized but are widely distributed geographically and
11 even when their geographic or electronic locations are
12 known, are hard to access because of proprietary and
13 liability and patient-confidentiality concerns and because
14 of system, file or protocol incompatibilities.
15

16 Even in the computer-abundant United States, in the mid-
17 90's, prescription writing is generally a manual process.
18 After consulting with a patient to determine their problems
19 and diagnosing, or attempting to diagnose their condition or
20 disease, a physician selects a drug and a dosage and an
21 amount to prescribe based upon their own personal knowledge
22 and experience, if necessary using available reference
23 materials which may or may not include promotional materials
24 from drug manufacturers. A prescription is then written up
25 under the physician's signature and bears a patient
26 identification, a drug name, dosage amount and timing,

1 refillability information and the physician's signature, the
2 date, possibly an advisory regarding contraindications, and
3 little other information. While a prescription may be
4 typed, keyed or otherwise "generated" on a computer most
5 prescriptions are still manually written.

6
7 Prescribing activity should be a good field for
8 computerization, but one difficulty is the lack of apparent
9 benefits to many physicians. Paper prescription pads are
10 small and easily carried around by a physician. Manually
11 writing a prescription will often be quicker and easier than
12 using a computer, however good the system. The benefits of
13 automated information systems often come not from greater
14 data entry efficiency, but from the increased efficiency of
15 the entire process, from the value of the transaction
16 records generated and also from the control of the
17 transaction entry process which may ensue. Physicians who
18 are not computer-literate or who are even "computer-phobic"
19 will require a most compelling reason to adopt a
20 computerized prescription management system.

21
22 To be fully effective, a prescription management system must
23 be readily usable by a wide range of physicians, preferably
24 for all their prescribing activity must provide compelling
25 value to patient care and increase overall treatment
26 management efficiency. Providing an attractive computer-

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1 More recently, small handheld or palm computers known as
2 personal digital assistants or personal information
3 communicators have become available. An example is the
4 Apple NEWTON (trademark). As of summer 1994, these are
5 rather rudimentary devices as compared with desktop or full-
6 powered portable systems, having modest permanent and RAM
7 storage capacities and limited processing and communications
8 abilities. Attractive to busy mobile professionals for
9 their small size, such handheld computers can also embody
10 highly desirable radio wave or infrared wireless
11 communications abilities enabling them to exchange data with
12 host systems without the cost or inconvenience of hard
13 wiring.

14
15 Such portable hand held radio communicating computing
16 devices are attractive for computerizing mobile
17 professionals such as physicians, but their processing and
18 storage limitations represent a real problem in providing a
19 sophisticated, capable and attractive system for physicians.

20
21 A broad objective of this invention is to provide a
22 prescription management system that can be used by
23 physicians on such mobile computing devices.

24
25 Simply delivering a system on a convenient portable computer
26 will not be enough to assure its regular use by a majority

1 of physicians. Though highly educated and technically
2 skilled, many physicians are not computer literate and are
3 averse to confronting a computer screen. Some may even be
4 intimidated by computers. Nor do their busy schedules
5 permit time to learn complex or difficult systems. Even for
6 an experienced user adoption of computer use into their
7 daily routines requires time change and adaptation. With
8 tremendous competition for their time, physicians will only
9 be willing to take these steps if they are enticed by
10 powerful system features that provides them with compelling
11 value to patient care and overall practice management
12 efficiency.

13
14 Nevertheless, the greatest of system features will be
15 worthless if the system hinders the professional in
16 executing routine functions. Even at sophisticated computer
17 products companies with access to, and experience with,
18 state-of-the-art systems, telephone sales staff often take
19 down orders with pen and pad rather than using an on-line
20 sales order systems.

21
22 An experienced professional practicing their specialty for
23 example a pediatrician treating infants knows from
24 experience exactly what to prescribe, in many instances.
25 They will have neither the time nor the patience to work
26 their way through conventional software selection and data

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1 entry procedures. Accordingly, a further object of this
2 invention is to provide a prescription management system
3 which personalizes itself to the prescribing patterns of
4 experienced users.

5
6 **SUMMARY OF THE INVENTION**

7 This invention solves a problem. It solves the problem of
8 providing a computerized, prescription management system
9 that an average prescribing physician can use and will want
10 to use and which makes possible significant improvements in
11 the quality of prescriptions written. In preferred
12 embodiments, the invention also solves the problem of
13 significantly reducing prescription costs to patients and to
14 their drugs benefit management company or government agency.
15 The invention solves these problems for physicians by
16 providing a prescription management system for electronic
17 prescription creation by a prescriber at a point of patient
18 care, said prescription being usable by a pharmacist to
19 dispense drugs, said prescription management system
20 comprising:

21 a) electronic posting means to select and capture in said
22 prescription:

23 i) a patient identifier;

24 ii) a prescribed drug;

25 iii) a dosage for said prescribed drug; and

26 b) a patient-condition treatment specification procedure;

1 whereby in creating said prescription said prescriber
2 specifies a patient condition for treatment by said
3 prescribed drug.

4 *Sub*
5 More generally, the invention provides a computer-based
6 professional product specification system for use by other
7 professionals, in addition to physicians, ^{and} which can deliver
8 substantial benefits to mobile ~~users who may be computer-~~
9 ~~inexperienced.~~

10 *Sub*
11 By associating a patient condition or problem with each drug
12 prescribed, a treatment objective is both expressed and
13 recorded, ^{and the} physician's intent ^{is captured.} ~~and deliver for physicians.~~
14 ~~the problem is solved by providing a user-friendly~~
15 prescription management system, ^{which requires} ~~requiring~~ minimal data entry
16 enabling ^{many} prescriptions to be created with an overall
17 efficiency unobtainable by ~~any~~ known automated systems and
18 which can helpfully supplement the skills of the best of
19 practitioners.

20
21 Pursuant to one preferred embodiment of the invention, the
22 drugs in the drug list are classified according to a patient
23 condition for which the drugs are effective and the onscreen
24 drug selection procedure lists multiple drugs for treating
25 each patient problem. In an alternative embodiment, the
26 user makes a drug selection by generic or brand name or some

1 other drug identifier, and the system supplies, suggests or
2 requires, entry of an appropriate treatment condition so
3 that the patient record is completed with the condition or
4 conditions for which the selected drug is prescribed.
5

6 The invention also provides a user-adaptive prescription
7 management system for electronic prescription creation by a
8 prescriber at a point of patient care, said prescription
9 being usable by a pharmacist to dispense drugs, said
10 prescription management system comprising:

11 a) electronic posting means to select and capture in said
12 prescription:

13 i) a patient identifier;

14 ii) a prescribed drug;

15 iii) a dosage for said prescribed drug;

16 b) a patient-condition treatment specification procedure
17 whereby in creating said prescription said prescriber
18 specifies a patient condition for treatment by said
19 prescribed drug;

20 c) an onscreen drug selection procedure having a patient
21 condition list specifying multiple possible patient
22 conditions, having a drug list specifying multiple
23 possible prescribable drugs and having drug
24 specification means to select and post a desired drug
25 to said prescription; and

26 d) tracking means to track preferred data usage by a user

1 and to adapt data displays to favor such preferred
2 usage, whereby the system learns and adapts to a user's
3 habits;

4 wherein drugs in said drug list are classified according to
5 a patient condition for which said drugs have efficacy and
6 said onscreen drug selection procedure lists multiple drugs
7 for treating each said patient problem.
8

9 Drug lists or individual drug selections or suggestions may
10 be presented to prescriber-users in any of a variety of ways
11 for example by frequency of prescription for a selected
12 condition, based upon either the user's historical
13 prescription activity or a wider base of historical
14 prescribing activity, which could be nationally or
15 regionally defined or derived from a drugs benefit house,
16 health maintenance organization, hospital or other
17 appropriate institution.
18

19 System suggestions for condition-related drug selection may
20 be further refined into categories such as relative cost,
21 generic or brand name and so on. Where many drugs are
22 available for treating a patient's active condition, one
23 particularly useful presentation is by multiple lines of
24 therapeutic preference according to drug formulary
25 guidelines. Thus, within the patient's particular formulary
26 there may be suggested first, second and third lines of

1 therapy. Different suggestions may be made for different
2 patients according to the preferences of the patient's
3 particular drugs benefit management company.
4

5 Preferably the system includes a comprehensive database of
6 approved drugs classified by conditions for which they are
7 known to have therapeutic effect and this database need not
8 be maintained in the users station but should be accessible
9 in real time to the user. Many valuable professional
10 benefits are obtained by delivering a selective listing of
11 drugs by condition to a physician. For example in treating
12 a particular chronic condition such as gastro-intestinal
13 disease, a physician may find that common medicaments such
14 as antacids are ineffective, that a particular brand name
15 drug such as TAGAMET (trademark) has, with prolonged use,
16 undesired side effects so that the physician may at this
17 point be interested in gaining information about alternative
18 drugs with which they are less familiar. If the physician
19 does not have the information at their finger tips, this
20 could be a time consuming process in their office reviewing
21 files and other archival information systems they have.
22 Alternatively on-line electronic services may be used but
23 this can also be a time consuming process. By offering a
24 comprehensive selection of drugs known to be effective for a
25 particular condition, this problem is easily solved for the
26 physician. The preferred embodiments include back-up

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1 prescribing information on each drug, along with details of
2 literature references supporting its manufacturer's
3 therapeutic claims or with means enabling the physician
4 promptly to obtain such references.

5
6 The invention is not limited to providing a prescription
7 management system. It can provide, in the medical field
8 alone, systems for clinical laboratory management, for
9 medical record management for radiology management and the
10 like. In addition the invention can provide novel
11 professional data management systems that can create new
12 products and yield comparable benefits in other professional
13 spheres where professionals are responsible for specifying
14 more or less complex technical products to solve client or
15 customer problems.

16
17 In this wider aspect the invention provides a professional
18 product specification system for electronically creating a
19 technical specification usable by a professional to specify
20 technical products said product specification system
21 comprising:

22 a) electronic posting means to select and capture in said
23 technical specification:

24 i) a customer identifier;

25 ii) a specified product; and

26 b) an onscreen product selection procedure having a

1 product benefit list specifying multiple possible
2 customer benefits having a product list specifying
3 multiple possible specifiable products and having
4 product specification means to select and post a
5 desired product to said specification;
6 wherein products in said product list are classified
7 according to a customer benefit which said products can
8 provide and said onscreen product selection procedure lists
9 multiple products for providing each said customer benefit.

10
11 **BRIEF DESCRIPTION OF THE DRAWINGS**

12 By way of example, some preferred embodiments of the
13 invention are described in detail below with reference to
14 the accompanying drawings in which:-

15 *Sub*
16 *96* **Figure 1** shows a system entry screen of a prescription
17 ~~management~~ ^{Creation} system embodiment of the invention
18 which system incorporates the screens of
19 **Figures 2-11;**

20 **Figure 2** is a patient selection screen;

21 **Figure 3** shows a prescription creation screen;

22 **Figure 4** is a condition list selection screen;

23 **Figure 5** is a condition selection screen;

24 **Figure 6** is a drug selection screen, condition
25 specified;

26 **Figure 7** is a nonformulary drug selection screen;

Figure 8 is an alternative condition-specification and drug selection screen;

Figure 9 is an alternative direct drug specification screen;

Figure 10 is a condition selection screen, drug specified;

Figure 11 is a drug selection evaluation screen;

Figure 12 is a single prescription history screen.

Figure 13 is a patient problem history information screen; and

Figure 14 is a manually updatable problem list maintenance screen;

Figure 15 illustrates a scheduled dosage drug package; and

Figure 16 is a schematic diagram of one way of connecting users of the prescription management system of Figures 1-14 with remote source databases across network to provide data and processing resources needed during operation of the prescription management system and useful inter alia for creation of a virtual patient record;

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Overview

The prescription management system illustrated in Figures 1-

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19

26 servers. As will be explained in more detail hereinafter,

3

1 especially with reference to Figure 16, the host computer
2 facility can call upon a variety of external resources and
3 functions as a marshalling and processing center for
4 organizing resources into useful and manageable pieces for
5 utilization by limited capacity user-interface devices. In
6 a preferred embodiment it is a co-ordination point on a
7 network for a number of user-device clients. Preferably the
8 network accesses or includes a number of remote database
9 sources providing useful information elements to the system.

10 *for capturing data*
11 Referring to Figures 1 to 14 of the drawings, the screens
12 shown employ user-friendly data selection and data entry
13 devices, such as are familiar to many computer users in Apple
14 Corporation's Macintosh® (trademark) and Microsoft
15 Corporation's Windows operating systems, for example
16 activatable buttons, pointers, scroll bars, icons, arrow
17 key, drop-down menus, windows and other screen symbols
18 designed for actuation by a pointing device, for example, a
19 mouse or trackball. More preferably, for compact "pocket-
20 book" computer applications, the pointing device is a pen or
21 stylus.

22
23 The prescription management system shown in this embodiment
24 of the invention has been designed for implementation on
25 physically compact, portable, user-interface devices such as
26 small portable personal computers, especially hand held

1 devices known as personal digital assistants. Those skilled
2 in the art will understand that the system can readily be
3 used on or adapted to other hardware platforms, for example,
4 a physician's desktop computer and can be expressed in
5 different software interfaces from that shown, especially
6 ones that use different input devices such as keyboards,
7 touch pads or touch screens and the like.

8
9 Pursuant to certain user-adaptive aspects of this invention,
10 the screens automatically personalize themselves, with use,
11 to adopt the patterns and habits of a regular user of a
12 particular device platform for the system, offering the user
13 their most frequently used information, drugs, conditions,
14 patients or patient groups, and so on as first line choices.
15 This adaptive characteristic is a valuable benefit endearing
16 the system to experienced users who may become impatient
17 with hierarchically accessed data.

18
19 Ease of use and suitability of the system to keyless or
20 minimally keyed platforms, especially PDA's is promoted by
21 minimizing the need for actual text or data entry by the
22 user and by emphasizing instead data selection from
23 extensive, preferably comprehensive, data lists. Preferred
24 embodiments of the invention allow quick pen selection of
25 data items through columnar pick lists.

26

1 The data lists, categories, groups, addresses or routes, can
2 be organized in multiple hierarchies for rapid and flexible
3 access to multiple large, remote databases, via multiple
4 access routes to retrieve multiple related data elements and
5 assemble them into a single data file, for example, a
6 patient history file compiled from the data resources of a
7 patient's historical health providers.

8
9 A desirable goal is to provide the physician-user with
10 intelligent data lists that are, where possible, exhaustive
11 and list, for example, all prescribable drugs, all
12 conditions, all formularies or all patients and present the
13 physician with helpful first-line choices or defaults
14 selected intelligently on the basis of historical data known
15 to the system. Preferably, the selection means is fully
16 system embodied, or automatic, operating transparently to
17 the user and requiring a minimum of configurational or setup
18 operations by the user.

19
20 Virtual Patient Record

21 An ability to compile what may be termed a "virtual" patient
22 record from multiple remote databases of primary source
23 information is a valuable novel feature of preferred aspects
24 of this invention. Such a virtual patient record can be
25 created in a chronologically current version by online
26 interrogation of all possible primary sources of

7 The record can be assembled dynamically, on an as-needed
8 basis, consulted by an authorized system user, and then
9 dissolved, without ever having been saved, giving the record
0 a virtual character.

Record element retrieval and record assembly are conducted under the auspices of the host computer facility employing a novel patient data directory service providing routing information to each patient's record elements. For each patient, the patient data directory service lists all institutions, including independent physicians, hospitals, HMO's, insurance companies, and so on, known to have source historical records on that patient, against a unique patient identifier, such as described hereinbelow. Also listed are routing or address data enabling the host facility to access institutional databases to retrieve record elements. Access protocols detailing, for example, what data can be accessed, when it may be accessed, by whom or by what organization or department it may be accessed, can be kept in a patient-specified directory, or elsewhere.

1 Patients not listed in the directory service can be searched
2 at the remote source databases and, optionally, at other,
3 host computer facilities supporting the inventive system for
4 other groups of users.

5

6 The complete, assembled patient history, or record, need
7 never be stored, unless the patient requests or consents to
8 such storage, and it serves some useful administrative or
9 care-related function. Storage or archiving of a record
10 that is potentially updatable from multiple uncoordinated
11 locations has the drawback of dating it. To become current,
12 the record must be refreshed from any database containing a
13 new data element for that patient.

14
15 By using a dynamically assembled virtual record, and never
16 storing it, potential problems of maintaining patient
17 confidentiality and preventing unauthorized access to highly
18 sensitive personal information can be mitigated or avoided.

19 This aspect of the invention avoids proliferation of a
20 patient's confidential history and permits primary source
21 data proprietors to act as exclusive wardens of their
22 individual confidential data elements.

23

24 Bio-pattern recognition

25 Bio-pattern recognition of personal user characteristics
26 including, for example, handwriting, signatures, voice

1 patterns and fingerprints is an attractive medium for
2 accepting user inputs, but in the present state of
3 development of the technology, suffers drawbacks which
4 disfavor use of bio-pattern recognition in preferred
5 embodiments of the invention. Future developments such as
6 greater processing capabilities in small user-interface
7 devices, and more accurate and efficient bio-pattern
8 recognition techniques may change this picture and favor
9 adoption of one or more forms of bio-pattern recognition.

10
11 Thus, handwriting recognition, is eschewed in preferred
12 embodiments of the invention, at the present time, because
13 writing is more tiresome to the user than pointing, pressing
14 or clicking and adds complexity and processing overhead to
15 the system. Additionally, handwriting recognition, although
16 presently available in pioneer systems, adds uncertainties,
17 may require significant user effort or adaptation and may
18 threaten data accuracy or promote user error.

19
20 Signature recognition may be desirable, if permitted by
21 regulatory agencies, for remote electronic authorization of
22 fulfillment at the pharmacy especially for mail order
23 prescription fulfillment and the pharmacy-prescriber link
24 can, if desired, add additional levels of security by
25 transmitting or exchanging supplemental electronic
26 identifiers.

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16 Adding higher performance hardware to support the processing
17 needs of handwriting recognition may be impossible with
18 available technology if a preferred lightweight, compact
19 form factor is to be retained for the user's device. An aim
20 of the invention is to provide a qualified prescribing
21 professional with a valuable tool that imposes no
22 significant burdens of weight or volume on the user, that
23 demands little of their time and yet can respond rapidly,
24 delivering valuable drug and patient information to the user
25 from remotely located, disparate sources. In other words,
26 an aim of the invention is to provide an intelligent,



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25 A still more preferred feature is to have user passwords
26 which link each user with an individual profile or style

1 sheet on the host computer facility representing the user's
2 patterns of preferences so that the user-customization
3 features of the system, which will be described more fully
4 hereinafter, are readily available to the user independently
5 of the particular interface device that happens to be
6 employed for accessing the system.

7
8 These and other device-independent features can permit the
9 prescription management system to be fully operative without
10 committing useful data to storage on the user device. This
11 is a valuable security feature. In the event of theft or
12 attempts at unauthorized use, even by skilled third parties,
13 a user device will be worthless as a means to access
14 sensitive data on the system or to use the system illegally.

15
16 Optionally, lost or stolen devices can be deactivated by the
17 application or by system software, after user notification,
18 by erasing or otherwise rendering device-resident
19 application procedures inoperable, without loss of device-
20 resident data. Use of a virtual patient record, as
21 described herein, which need not be stored locally, is a
22 valuable safeguard against unauthorized access of
23 confidential data on lost, stolen or "borrowed" user
24 devices.

25
26 Host computer facility

1 Currently contemplated preferred embodiments further control
2 the processing and storage demands placed on the user's
3 device by intelligently delegating data-processing and
4 storage activities to a linked remote, host computer
5 facility, as referenced above, to the extent warranted by
6 the capabilities of the user device. Thus, for example, a
7 comprehensive drug database may be stored and maintained on
8 such a host computer facility with selected data, for a
9 particular drug list or an individual drug's formulation
10 characteristics, being forwarded to the user's device on an
11 as-needed basis, then being eliminated from the user device
12 when no longer required. Other activities may
13 advantageously be performed locally on the device, such as
14 dynamic assembly of records from elements retrieved across
15 the network from remote storage, and storage of the user's
16 personal or most frequently referenced data and data lists,
17 where the device's capabilities permit.

18
19 Where the user device is more powerful than present-day
20 PDA's, for example a present-day desktop computer or perhaps
21 the PDA's of the future, more processing and data storage
22 functions can be retained at the user device rather than
23 delegated to the network. Although permanent (disk,
24 diskette or flash memory) storage may have uses, security
25 concerns can be better managed on the network than on the
26 user device, so that it is preferred that minimal data be

1 work flow.

2

3 In addition, the screens are laid out in the manner of
4 appealing logical forms that echo familiar data formats
5 encountered by a physician in their day-to-day work. An
6 important objective is to make the screens self explanatory
7 within the professional's normal terms of reference so as to
8 avoid any need for access to help, although of course, HELP
9 buttons can be provided if desired and extensive help
10 documentation can also be provided. System utilities such
11 as indexing, setup and purging are either concealed from the
12 user or removed for execution on a remote host computer
13 facility. Data integrity and availability responsibilities
14 are also delegated to the host computer facility, or its
15 remote data suppliers. Thus data saving, archival, backup
16 and data-replication functions are host facility
17 responsibilities, not concerns of the user.

18

19 The system is designed to require a minimum of actual text
20 or data entry. So far as possible, item entry is effected
21 by selection from lists of items, for example by
22 highlighting an item, then clicking a mouse, or more
23 preferably penning, to activate an item.

24

25 The prescription management system is made as user-friendly
26 to physicians as possible, for example, by using familiar

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1 professional terminology and abbreviations. Thus terms such
2 as "Patient" or "Pt", "Drug" or "Rx", "Condition" or "Dx"
3 and "Treatment" or "Tx" are used rather than confusing
4 generalities such as "subject" and "item" that often appear
5 in generic software. The Prescription Management System
6 shown in this embodiment of the invention has been designed
7 for use with small portable personal computers, especially
8 hand held devices known as personal digital assistants.
9 Those skilled in the art will understand that the system can
10 readily be used on or adapted to other hardware platforms,
11 for example, a physician's desk top computer and can be
12 expressed in different software interfaces from that shown.
13
14 Referring now to Figure 1 the system entry screen
15 illustrated has a user-customizable button bar 10 which has
16 been set with a conventional Quit button 12 and a Help
17 button 14, along with a Mail button 16 for accessing an
18 electronic mail ("E-Mail") system, a Prescribing button 18
19 for accessing the prescription management system embodiment
20 of the invention, an Encounter button 20 for accessing a
21 patient encounter management system (not further described
22 herein). Ans Svc button 22 accesses an answering service
23 screen (not shown), which as a convenience function can be
24 dynamically linked via the host computer facility to log
25 incoming calls for the user. The answering service is
26 preferably intelligent and prioritizes, by flagging or

1 displaying, patient- or treatment-related calls, for example
2 those from a pharmacy, while screening out or de-prioritizes
3 less relevant calls.
4

5 History-cognitive drug and condition listing

6 A Doctor's Lists button 24 accesses a more or less complex
7 ^{library} display of patient condition and therapeutic drug lists.

8 Preferably, the drug and condition lists are linked together
9 to associate a drug with one or more conditions for which it
10 might be prescribed and, in most cases to provide the
11 physician user with a conveniently displayed, concise
12 selection of drugs for treating any particular condition.

13 In a preferred feature of this invention, the system has a
14 user-adaptive character and adapts itself to the user's
15 habits and prescribing patterns so as to service the user
16 more efficiently. To this end, the drug lists or the

17 condition lists, or both, are ^{system-generated and} ^{block 123 (Fig. 21)} system-modified with use to
18 reflect the prescribing frequency of particular drugs ^{block 87} or the
19 frequency of occurrence of particular conditions. ^{block 89} Thus,

20 more frequently prescribed drugs or more frequently
21 encountered conditions can be presented to the user
22 physician in a more prominent manner or more immediate
23 manner than ones found by the system to be historically less
24 common in the particular user prescribing environment. In
25 this way the system becomes more valuable with use as the
26 drug and condition lists develop into personalized lists

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1 featuring the user's preferences.

2

3 With such cognitive features the inventive system is
4 effectively cognizant of ongoing prescribing activity. It
5 comes to know its user's environment and preferences, can
6 adapt itself to any number of specialist situations, and
7 can, if suitably equipped, subtly prompt the user, online
8 with original, relevant, but elusive information derived
9 from the user's computer-memorialized practice experience.

For example the system may prompt the user that the last time Drug X was prescribed for Condition Y, Patient Q reported adverse reaction Z. Where the host computer facility documents a catalog of known adverse reactions to system-listed drugs, a system enhancement can report new adverse reactions to the user or centrally, to the host computer facility, by tracking logged patient conditions and relating them, where appropriate, to a previous prescription. In similar manner the system may log drug-drug interactions, which interactions can also be associated with a target condition or conditions. Many other valuable retrospective statistical studies and analyses are made possible by deployment of the invention, as will be apparent to those skilled in the art. While such studies are potentially of immense public value if widely implemented, careful controls will be required to avoid reporting unrelated conditions as adverse drug reactions.

:

16 Of commercial note is that the foregoing data may be
17 aggregated for multiple users, for example by the host
18 computing facility, for market research purposes. Also, an
19 individual user's prescribing patterns may be reviewed by
20 the user or by others. For example, drug benefits
21 companies, can review the user's prescribing patterns for
22 formulary compliance and respond by encouraging better
23 compliance, where appropriate. Release of such data to
24 third parties can be controlled to safeguard the privacy of
25 the prescriber, or other health care provider, by
26 prescriber-determined data access protocols specifying who,

1 of care, enabling a physician to draw upon the following
2 categories of data:

- 3 i) physician-user prescribing-frequency data;
4 ii) patient drug formulary information as to a drug's
5 status with a patient's drug benefits provider;
6 iii) drug dosage characteristics, for example, form,
7 size, route of administration, amount, frequency
8 and the like;
9 iv) drug-specific treatment information as to
10 condition-related efficacy, and preferably as to
11 contraindications and adverse reactions;
12 v) relevant patient history information as to current
13 and previous prescriptions, and preferably also,
14 pursuant to the teaching of the present invention,
15 problem-history information; and
16 vi) laboratory and other diagnostic test information
17 related to the patient's indications, to dosing,
18 to therapeutic choices or to specific drug
19 selections.

20
21 Preferably, this data is brought to the point-of-care by
22 relying upon retrieval from remote source databases at
23 remote facilities responsible for capturing original update
24 data, and not by relying upon redundant non-source data
25 requiring constant synchronization with source data to
26 remain current.

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1 Diagnostic tests

2 Items i)-v) above, will be described in considerable detail
3 hereinafter. With regard to diagnostic tests and
4 procedures, for example radiology, the invention
5 contemplates electronically bringing relevant information to
6 the point of care to assist health care providers make
7 informed decisions. Such diagnostic information may
8 comprise recommendations for clarifying a tentative
9 diagnosis, or choice of diagnoses, or may comprise
10 diagnostic results that can be used to make more informed
11 therapy decisions and, in particular, to make better
12 therapeutic drug selections. Body system function tests,
13 for example renal or liver function tests are clearly
14 valuable to a drug selection process, since renal and liver
15 condition are important in determining dosages of some
16 medications. Other therapy-relevant diagnostic
17 determinations can usefully be presented at the point of
18 care, by means of the present invention, for example, drug-
19 level determinations can enhance dosing decisions.
20

21 Patient encounter program

22 A useful, prescription management system-compatible patient
23 encounter program can begin with a patient selection screen
24 such as that of Figure 2. The patient selection screen of
25 Figure 2 can be activated by any one of multiple programs
26 which may, for example, be initiated via the system entry

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substantial savings of resources, time and effort by using only source data for patient records, minimizing creation of multiple redundant local databases that require constant synchronization with remote sources if they are to remain accurate and up to date.

0 The invention also provides novel data-retrieval network
1 systems to retrieve relevant patient data elements from
2 multiple remote heterogenous primary source databases.
3 Preferably, the system is configured to retrieve data from

14 call from a user device for a patient history or patient
15 record, relevant data elements, for that record, or a record
16 component (e.g. the most recent six-month or twelve-month
17 portion), are retrieved from remote source databases,
18 dynamically assembled, or integrated, into a virtual patient
19 record, as described above, and delivered to the user device
20 as an integral system data set. Alternatively, record
21 assembly, which does not require undue hardware resources,
22 can be performed on board the user device.

25 with patient authorization, but does not need to be
26 permanently stored.

1 The host computer facility responsible for dynamic assembly
2 of the virtual record logs the time, date and calling user
3 to provide an audit trail of access to the patient's record,
4 but does not commit the record to permanent storage. After
5 use, the virtual patient record disappears, although it can
6 be reconstructed archivally.

7
8 If the record is required again, it is assembled anew,
9 thereby incorporating any updates that may have occurred in
10 the interim, for example changes in drug benefit status,
11 insurance coverage or the like, newly generated laboratory,
12 radiology or other diagnostic results, or other, e.g.
13 emergency, prescriptions dispensed. The act of assembling a
14 record externally of its sources immediately dates the
15 record: it is cut off from any updates, and therefore liable
16 to become incomplete, obsolete or dated. Virtual patient
17 record assembly, as described herein, avoids this problem
18 making local storage of patient records unnecessary.

19
20 Transactions are archived by the host system to provide a
21 complete transaction history, so that past activity can be
22 reconstructed. Such a data-reconstruction capability to
23 provide clear hind vision of the patient's record at any
24 given time is an important medicolegal capability. That
25 historical version is preferably reconstructed from a
26 transaction log and assembly of timed and dated record

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1 examination of any desired historical records, such as may
2 be required for review or legal purposes.

3

4 Using the above-described method of dynamic retrieval from
5 remote databases across a data-retrieval, record-integrating
6 network, source database proprietors can remain wardens of
7 the only copy of that data and obtain patient authorization
8 to be the sole repository of that data. Laboratories can
9 keep laboratory records; insurance companies can keep
10 insurance records; hospitals can keep hospital records; and
11 health maintenance organizations can keep their own records;
12 without ever having to release copies of these records into
13 external electronic storage by third parties, with the
14 security hazards attendant upon such releases. Any
15 electronic release made externally using the data access
16 control features described herein can be assured of always
17 being authorized by whatever entity, be they patient,
18 physician or organization, that has proprietary rights in
19 the data.

20

21 Figure 2: Patient selection screen

22 Upon selecting Prescribing button 18 by clicking or pen
23 contact, a patient selection screen, for example as shown in
24 Figure 2, is displayed as a preliminary to prescription
25 management functions. Referring to the patient selection
26 screen of Figure 2, the name, age, gender, and social
and the flow diagram of Figure 17

19
20
21

Select Patient screen 44

^ New
^ The
^ the

26 If desired, preliminary selection of groups of patients can

1 be made by providing various patient lists, for example
2 "Today's Patients", "In-Patients", "Out-Patients", "Private
3 Patients" and the like. Such patient lists are preferably
4 system-maintained, on an ongoing basis, using the latest
5 data available to the system and preferably enable the user
6 to select a convenient group of patients that has a high
7 probability of including the next patient or patients to be
8 encountered, thereby speeding access and retrieval of a
9 desired patient record. Where the user typically encounters
10 patients in groups, for example one group in an out-patient
11 clinic and another group in an in-patient clinic, such
12 grouping of patient records into lists also facilitates
13 organization by a host computer facility of display data
14 into small batches that can more rapidly be communicated via
15 limited capacity copper wires and modems and are of a size
16 that can conveniently be held in RAM on a small, portable
17 user device.

18
19 Patient Data Security

20 Critical to public confidence in the prescription management
21 system of the invention are issues of security, since the
22 system requires access to personal records. Many people
23 will fear unauthorized access to or use of their personal
24 information. Preferably, the invention provides careful
25 controls to alleviate such fears and to prevent unauthorized
26 access to a patient's data or to their physician's

1 prescribing profiles.

2

3 Preferably also, the system, or an associated support
4 network, provides data access controls such that the only
5 accesses that can occur are those that have been authorized
6 or preauthorized, at a point of care or elsewhere, in
7 accordance with security profiles on the network established
8 on behalf of data-proprietor entities such as patients,
9 physicians or organizations. It is further preferred that
10 the entity's security profile, or filter, details what data
11 can be accessed, when it may be accessed, where it may be
12 accessed and by whom it may be accessed.

13
14 Various suitable data access control measures will be known
15 to those skilled in the art and considerable security can be
16 obtained by using more or less complex identifiers for
17 patients or for physician-users of the system or for both.

18
19 Patient records should use a standard identifier to be
20 clearly and distinctly identified with a confidence level
21 appropriate to the expected patient population in the
22 lifetime of the system so that the records of patients with
23 similar or identical names are not confused. If desired, a
24 coded alphanumeric patient identifier (not shown) may be
25 used. Alternatively, or in addition, other unique patient
26 identifiers such as social security numbers may be used

3

11

20

25

Patient-directed control of the flow of their own data, a

3

21 Many similar data security considerations apply to
22 prescriber-related data. Used comprehensively, as it is
23 intended to be, the system is privy to full particulars of a
24 physician user's professional prescribing behavior, day in,
25 day out, potentially throughout their career. System
26 resources may be used to compile any desired historical

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1 by various third parties for example health maintenance
2 organizations (HMO's), hospitals, government agencies,
3 managed care organizations and so on.
4

5 A particular group to whom a prescriber may wish to yield
6 access rights comprises collective bargaining associations,
7 for example independent practitioner associations, preferred
8 provider organizations and physician hospital organizations.
9 Preferably, all accesses to a prescriber's data are system
10 stamped with a date, time and accessor ID, to create an
11 audit trail of such accesses, similar to the audit trail
12 left by accesses to patient data.
13

14 System-determined access control can be invoked, whenever a
15 prescriber data access request is received, by referencing
16 the prescriber's access control file and permitting or
17 denying access in accordance with the file's specifications.
18

19 Prescription creation screen 39

20 Referring to Figure 3, prescription creation screen 39 has a
21 full array of user-activatable buttons enabling a physician
22 to draw on powerful resources within the prescription
23 management system ^{as well as} ^{resources} and supporting it in the host computer
24 facility and associated data-retrieval network, as will
25 shortly be described. Near the top of screen 39 is a
26 patient features bar 40 below which a prescription features

1 bar 42 coordinates all features necessary to review current
2 therapy and order changes in treatment, or order new
3 treatment, for the selected patient. A prescription history
4 zone 43 extends across the middle of the screen, the lower
5 screen portion contains a prescribing zone 44, and a screen
6 title 45 appears at the top of the screen.

7 *SWR*
8 *alt* Patient features bar 40 comprises a Select Patient button
9 46, a selected patient indicator 48, in this case Mary
10 Harrington, a patient Problems button 50 and a patient
11 Allergies button 52. Beneath Problems button 50 are
12 displayed Mary Harrington's currently active problems 51 or
13 conditions, shown here as pharyngitis and bronchitis.
14 Beneath Allergies button 52 are displayed Mary Harrington's
15 known allergies. Pressing or otherwise activating Problems
16 button 50 or Allergies button 52 ^{ca} opens a window or screen
17 listing problems or allergies from which a physician, or
18 other professional user, can select new problems or
19 allergies to add to Mary Harrington's record, or delete ones
20 that are no longer active. Optionally, system-provided
21 problem or allergy libraries may be organized into multiple
22 lists with button 50 or 52, respectively, opening a list
23 selection box as a preliminary to displaying a selected
24 problem or allergy list.
25
26 Problems or conditions 51 and allergies 53 are here

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22 Prescribing zone 44 comprises three active buttons, New Rx
23 button 78, Send Rx button 80 and Close button 82, below
24 which extends a prescribing header bar 84 which contains
25 field identifiers for data entry of a full complement of
26 prescription details. Available prescription detail fields

1 comprise a Condition field 86, a Drug field 88, a Generic
2 field 90, a Form field 92, a Size field 94, a Route field
3 96, an Amt (Amount) field 98, a Refill field 100, a Dosing
4 field 102 and an Expires field 104.

5
6 Multiple lines of the selected patient's prescription
7 history are listed in patient history zone 43 in the middle
8 of the screen for convenient review by the physician-user,
9 and possible renewal, with scrolling or paging of extensive
10 histories. Depending upon the patient's previous
11 whereabouts and service providers, individual lines may come
12 from multiple remote sources. Such histories are preferably
13 compiled by the host computer facility in response to a call
14 from the user device (see the description of Figure 16).

15
16 *Sub* Prescribing zone 44, lower down prescription creation screen
17 39, allows a physician user to select and prescribe drugs
18 and dosages, for the selected patient, in this case Mary
19 Harrington, and to transmit the created prescription *by activating the Send Rx button 80,*
20 externally across a data network to other interested and
21 authorized parties for prescription fulfillment, *block 85* patient
22 record updating *arrow 57,* and the like. *1*

23
24 Select Patient button 46 returns to the patient selection
25 screen of Figure 2 for selecting a different patient from
26 one or more lists. Preferably, Select Patient button 46

1 draws up a "Today's Patients" list or whichever patient list
2 the user last selected from, or a default, user-selected
3 patient list, and provides the options of selecting a new
4 patient from alternative patient lists.

5
6 **Problems** button 50 brings up a patient problem history
7 information screen such as that shown in Figure 12 (to be
8 described) in which a historical record of the patient's
9 individual symptoms and diagnoses is listed and to which new
10 problem reports can be posted. To maintain data integrity,
11 and as a legal safeguard, historical information is not
12 editable but may be supplemented, for example by reporting
13 the subsequent status of a problem as (still) active or
14 inactive. Preferably, any such additions to the record are
15 stamped with the identity of the reporting physician,
16 providing valuable elements of a treatment decision-making
17 audit trail.

18
19 ~~The patient's drug-related allergies, or drug reactions, are~~
20 ~~brought up in possibly editable form (screen not shown) by~~
21 ~~activating an Allergies button ⁵² 48 and may be automatically~~
22 ~~system updated, if desired by adding newly reported drug~~
23 ~~reactions and allergies. ⁵¹ Desired personal or drug records~~
24 ~~relevant to possible allergies of this patient may be~~
25 ~~summoned from the host computer facility, which may in turn~~
26 ~~call on the remote database data-retrieval network for~~

Sub
all
52
48
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block 41 (Fig 17)
over

1 records or record elements.

2

3

4 Rx History button 54, scrolls, drops down, or otherwise
5 accesses any additional patient history lines beyond what
6 will fit in prescription history zone 43 and may introduce
7 vertical or horizontal scroll bars, or both, into zone 43,
8 enabling the user to display any desired section of a
9 patient's prescription history in zone 43 with the top line
10 of the history highlighted. Any desired prior prescription
11 line displayed in zone 43, can be highlighted by clicking or
12 pressing on it.

13

14 *Sub* A highlighted prior prescription can be automatically
15 renewed by clicking or pushing an Renew Rx button 62.
16 Typically, prescription creation screen 39 opens with the
17 most recent prescription highlighted for possible renewal.
18 Activating Renew Rx button 62 posts a highlighted prior
19 prescription into prescribing zone 44 for automatic renewal,
20 after editing, if desired. Renewal of any prior
21 prescription can thus be effected in as few as two user
22 steps by pressing Renew Rx 62 to post a highlighted
23 previous prescription to prescribing zone 44 and a single
24 ~~further action to complete~~ *Completing* a prescription *in a single step* from there. If
25 desired option buttons such as Renew and Send Last
26 Prescription or Renew All Active Prescriptions can be added.

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1 Pressing header buttons Condition 64, Drug 66, or Expires
2 74 causes the drug history display to be sorted by the
3 selected header enabling the prescription history to be
4 evaluated according to a particular parameter. This feature
5 is of particular value for patients with long and complex
6 treatment histories.

7
8 An important novel feature of the inventive prescription
9 management system is the ability to associate a specific
10 patient condition with each drug prescribed. By capturing
11 detailed information on every prescription the system
12 automatically builds a novel patient medical record having
13 new uses in evaluating individual patient treatment and in
14 enabling powerful new, multi-center outcome studies for
15 evaluating therapies in various populations of patients.

16
17 By deploying the inventive system regionally, nationally or
18 in some other population area, and employing the preferred
19 methods for retrieving patient data from remote sources, as
20 described herein, a complete patient record of all activity
21 within a region can be built. Preferably this is a virtual
22 patient record dynamically assembled only from original
23 source data, which, as described above, is maintained in
24 component form at multiple distributed source databases, is
25 retrieved therefrom across a data-retrieval network from
26 which the source databases can be accessed, and is compiled

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SECRET

3

Careful review of a patient's record for relationships between amelioration of problems and prescription of particular drugs can provide important information about the efficacy of a drug for a particular problem in a given patient. Review of a physician's prescribing record, detailing the various drugs selected to treat the different conditions exhibited by the patients encountered in the physician's daily practice, can reveal valuable information about the physician's prescribing practices and the degree to which they follow formulary guidelines.

This information is clearly of value to the individual physician and can, if desired, be enhanced by including in

1 the problem record a condition severity rating, enabling
2 declines (or increases) in severity to be reported. The
3 resultant patient prescription history, replete with dated
4 information as to patient problems, what drugs were
5 prescribed to treat those problems, what forms, routes of
6 administration and dosages were used and, by implication
7 from the timing and nature of subsequent problems, what the
8 outcome of that prescription was, provides a very attractive
9 treatment evaluation tool to a physician, and a powerful
10 inducement to any professionally conscientious physician to
11 use the prescription management system of the invention.
12

13 Implementing the invention on a wider scale, valuable new
14 outcome studies and clinical trials are easily, or even
15 automatically, performed. One of many problems in
16 successfully implementing the herein described prescription
17 management system on a large scale is one of funding the
18 system. Medical cost structures, with their reimbursement
19 systems leave little scope for expenditure on aids to
20 overall practice improvements which may have to be squeezed
21 out of tight overhead budgets. Accordingly, significant
22 cost to the physician user, or user's medical facility will
23 be a major deterrent to system adoption. Preferably the
24 system is provided to prescribing users on a low-cost or no-
25 cost basis with funding from outside sources.
26

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Implementation of the invention is expected dramatically to
2 reduce the overall cost of prescriptions and this saving has
3 been estimated to be from 20 to 40 percent of total
4 prescription costs. Savings will accrue initially to the
5 drug benefit management companies who reimburse the direct
6 costs of most prescriptions, but can be expected eventually
7 to be passed to corporations and consumers by way of lower
8 drug benefit rates. Such savings realized on a national
9 scale would amount to many billions of dollars and provide
10 an avenue of reimbursement for system proprietors. In the
11 early 1990's, the cost of prescription drug benefits is one
12 of the fastest rising components of all health care costs.

a7

14 Outcome studies produced by the system may have substantial
15 value to various parties, and their sale can support system
16 costs, as may formulary compliance savings. For example,
17 drug efficacy data is of value to pharmaceutical companies,
18 as is early warning data from reliable specialists regarding
19 adverse reactions. Subject to confidentiality and other
20 relevant controls, such data can be automatically compiled
21 and readily supplied by system management, requiring only
22 approval, not active participation by involved physician
23 prescribers. Equally, the system may facilitate clinical
24 trials by identifying health care providers or prescribers
25 who would be likely participants in trials, based upon their
26 having frequently diagnosed relevant conditions, or

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3

1 would be indicated for *H.pylori*-negative gastritis.

2

3 The system can also provide, preferably from source
4 databases, complete prescription drug disclosure
5 requirements as set forth by the FDA, including full
6 cautionary information, for example as is now set forth in
7 the Physicians' Desk Reference (Medical Economics) and
8 Physician's GenRx (Denniston Publishing) knowledge of which
9 by the prescriber may be necessary to avoid malpractice
10 liability, and dissemination of which may limit a drug
11 manufacturer's liability. Efficient promulgation of drug
12 disclosure information to system users is tantamount to
13 publication, yet can be more current than any printed
14 document, and may be accepted as an alternative to hard copy
15 publication or supersede it.

16

17 In addition, the system provides a valuable means for
18 government agencies and others to communicate important
19 messages, such as drug warnings and alerts, quickly and
20 directly to physician users. Electronic mail accessed via
21 Mail button 16 can be used for this purpose, and may include
22 priority flags triggering screen alerts, but a much more
23 powerful route for communicating warnings relating to
24 particular drugs is to associate the alert with system
25 information on the drug so that when a user calls up the
26 drug in question, they receive the warning or alert, or

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1 other special message.

2

3 In the extreme case of withdrawal of a drug from the market,
4 that fact can immediately be communicated to system users.

5 Thus a drug can be withdrawn from the market the same day by
6 making a system entry preventing completion of a

7 prescription for the withdrawn drug. Alternatively, a

8 warning can be posted directly to the prescription. Current

9 users of the medication can be identified from prescription

10 history records, referencing not only drugs prescribed, but

11 also prescription expiration dates. Both the patient and

12 their doctor can be notified immediately. In this case,

13 electronic mail is a preferred route for notifying the

14 physician.

15

16 Relative cost-to-benefit data can also readily be prepared

17 in outcome studies when individual drug costs are factored

18 into the data, and such cost:benefit data can, in some

19 circumstances have very substantial dollar value to drug

20 benefits management companies whose objectives are to

21 maximize the quality of care while minimizing the cost of

22 that care.

23

24 Pharmaceutical and managed care companies can gain marketing

25 benefits from use of the system to introduce new drugs or

26 new uses of old drugs to physicians, in a relevant manner,

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1 at a moment of peak interest.

2

3 Other benefits can be derived from outcome studies using the
4 novel drug-prescribed and condition-treated data records
5 provided by the prescription management system of the
6 invention. For example, the appearance of a new patient
7 problem may be insignificant when associated with prior
8 prescription of a particular drug for one patient, but may
9 gain significance when repeated for a number of patients.

10

11 Optional system enhancements may enable post-introduction
12 market surveillance of new drugs to be conducted for adverse
13 outcomes to the treatment of a specified condition or
14 conditions. For example the system may monitor patients
15 reporting new problems after having been prescribed the new
16 drug in question, refer such new problems to the physician
17 user to qualify them for medical relevance and then
18 statistically compare a collection of similar reports with
19 data on a pool of similarly treated patients for
20 significance.

21

22 *Sub*
H 229 Continuous post-market-introduction monitoring of a drug in
23 relation to the treatment of conditions is possible, and an
24 end-to-end solution to the problem of managing unanticipated
25 problems arising with new drugs can be provided: the system
26 provides a vehicle ^{for} data collecting relevant data; parameters ^{for each}

over

22

22

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3

3

Compilation of an extensive or national database of (patient-anonymous) records providing a statistical historical listing of drugs prescribed versus associated conditions for which they were prescribed would be in the public interest and of considerable value, so long as patient-confidentiality were maintained. Widespread adoption of the present invention can help achieve this desirable goal. It is relevant to note that FDA regulations only permit a drug to be promoted for approved, specific therapeutic purposes but physicians are professionally free to prescribe an approved drug for any condition for which

1 they believe the drug to be effective or useful so that,
2 failing specific point-of-care diagnostic information, no
3 assumptions can be made as to the treatment objectives of
4 any particular prescription. Accordingly, prior to the
5 present invention, statistical prescribing data have
6 generally lacked knowledge of why a physician prescribed a
7 particular drug, and such data is, in most cases, not useful
8 for outcome studies and cannot be related back to other
9 patient-specific variables present in the patient's medical
10 record.

11
12 Prescription history record

13 Referring to the prescription history zone 43 of the Figure
14 3 screen, under the Condition field 64 is listed a condition
15 reported as active when the drug was prescribed. Drug field
16 66 may be a generic name or a brand name. The Size field 68
17 is the dosage size. Dosing field 70 shows the dosing
18 frequency. The "G" flag 72 is for generic and is a simple
19 yes/no indicator. An Expires field 74 displays an
20 expiration date system calculated from the prescription
21 quantity (not shown), the size and the dosing rate and
22 indicates the day on which the prescription will run out.

23
24 The last column, Mine field 76, is a yes/no toggle flag
25 indicating whether the prescribing physician was the current
26 system-designated physician user ("Y" = my prescription) or

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Update button 58 can be a simple blinking indicator alerting the user that their device is communicating with the host computer facility and actively processing a local update. To indicate additional time taken accessing remote databases, the message can change to "Remote Retrieval", if desired. Additionally, Update button 58 can activate various update options, selectable from a menu, if desired. For example, Update button 58 may offer a selection of different sources from which to update the patient's prescription history. While a preferred objective of the invention is that the prescription management system obtain a comprehensive, nationwide update of any previous prescribing activity regarding this selected patient, considerations of system speed, system development or marketing considerations may make it desirable to offer patient prescription histories drawn from all prescribing activity in a more limited geographical region, for example,

1 Pressing (or clicking on) highlighted fields beneath the
2 headers in prescribing header bar 84, in most cases,
3 activates pull-down menus, or data entry scrolls. Generic
4 field 90 is merely a toggled flag while Expires field 104 is
5 a system-calculated field. Although provision can be made
6 for a physician to make original entries, the preferred
7 embodiment provides a comprehensive selection of system-
8 generated drug prescribing data from which the user may make
9 selections.

10
11 If the user knows the drug they wish to prescribe, the drug
12 name may be keyed in or, preferably selected by highlighting
13 and clicking from one or more intelligently maintained lists
14 presented in drop-down menus to post it to the respective
15 highlighted field under Drug header 88. Alternatively, the
16 user can select a condition from a condition list and make a
17 drug selection appropriate to that condition from a drug
18 selection screen such as those shown in Figures 4 through 11
19 as will shortly be described in more detail.

20
21 Generic flag 90 is a simple yes/no indicator which is linked
22 to each drug selection to approve generic drug substitution
23 for brand name drugs by the pharmacist, if such substitution
24 is permitted by state regulation.

25
26 Prescription quantification

11

19

23 The Amt field 98 is the amount or quantity of drug to be
24 dispensed in the prescription, for example 30, 50 or 100
25 capsules or 50, 55, or 100 ml of liquid. Refill field 100
26 shows the number of times refilling is permitted and Dosing

5

20

22 Referring to the embodiment illustrated in the drawings,
23 **Expires** field 104 can be system-calculated field from the
24 entries in **Amount** field 98 and **Dosing** field 102, to indicate
25 the day on which the last dose will be taken.

26 Alternatively, the physician-user can select, or enter, an

1 As stated above, a preferred objective of the invention is
2 to minimize need for keyed data entry, to minimize
3 information look-up, or preferably to avoid all need for
4 keying, by providing a comprehensive system interfacing with
5 the user through easily operated data entry devices such as
6 employed in pen-based computer devices. To achieve this
7 end, the prescription management screen of Figure 3, is
8 preferably supported by comprehensive, fully adequate, up-
9 to-date databases of drug information that, in a
10 particularly preferred embodiment of the invention, provide
11 a physician user with substantially all available relevant
12 prescribing information on drugs, especially on those drugs
13 they write most frequently, which may be favored with
14 preferential device storage on the user's interface device,
15 for rapid retrieval. Relevant prescribing information on
16 other drugs, written less frequently, or not at all by that
17 user is available on the network.

18
19 Prescription fulfillment

20 When drug specification is completed to the physician's
21 satisfaction, Send Rx button 80 is pressed to output the
22 newly created electronic prescription in any desired form
23 such as to print, to local or remote storage or to remote
24 file transfer as an electronic prescription. The electronic
25 prescription can be transmitted across a network for
26 fulfillment by any specified pharmacy, for example, the

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3

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16 Ensuring that a patient complies with the terms of a
17 prescribed treatment, neither neglecting nor overindulging
18 in a prescribed drug therapy, is a serious problem in health
19 care management. It is difficult to ensure that out-
20 patients actually ingest the prescribed amounts of
21 medication at the prescribed intervals. Many mistakes and
22 abuses occur. The problem is exacerbated when a patient is
23 prescribed a confusing multiplicity of drugs that may have
24 to be ingested in different amounts at different times of
25 the day. The present invention enables, and includes,
26 unique solutions to this problem that greatly facilitate a

Another approach is, to some extent, inherent in features of the prescription management system described herein. Where multiple physicians accessed by a patient utilize the system described herein, with common online access to, and assembly of, a patient's prescription history record whereby that record provides a current record of new prescriptions, then a common abuse can be controlled wherein a patient presents a problem or condition to more than one physician to obtain multiple prescriptions with a view to indulging in abusive ingestion or illicit resale. This problem is especially prevalent with analgesics. Where a physician, or perhaps pharmacist, if the patient's prescription history is available to the pharmacist, sees a similar current prior prescription has been issued, they can refuse to duplicate it.

Bringing fulfillment information from the pharmacy to the point of care via the patient's record or other convenient reporting medium, with or without the intermediary of a drug benefit company linked as a remote source database, can provide not only a valuable prescription abuse monitoring parameter but can also be used to enhance compliance with the prescribed treatment, especially if coupled with an alerting system.

For example, the system may alert a prescriber that the intended expiration date of a critical prescription has passed without the prescription having been filled. The prescriber thus becomes aware that the patient has gone off the medication and can take steps to contact the patient and

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1

1

24 Figure 15 shows a scheduled dosage drug pack 182 configured
25 as a daily pack with the day of the week prominent and the
26 date, patient and doctor identified. Across pack 182 run

three multi-compartment drug bays 184 each of which can accommodate up to four different solid drug formulations 184, pills, capsules, tablets, caplets, or the like and is sealed by a tear strip having an opening tab 186. Each bay is clearly labeled with a time of day at which the dosage in each bay 184 should be taken. Vertical zones 188 are dedicated to an individual drug and comprise a header with a drug name and special instructions (take with water, after food, and so on) and a compartment in each bay 184 for each dosage time. To demonstrate the flexibility and dose-organizing power of this novel, pack-based system a first drug is shown schematically in lefthand zone 188 with thrice-daily dosing, a second in left central zone 188 with twice-daily dosing and a third in right central zone 188 with once-a-day dosing. Righthand zone 188 is not used, but could be occupied by a fourth drug, the individual dosages of which are loaded into those individual compartments of Righthand zone 188 that correspond with desired dosage times or intervals.

Clearly, modified drug packs 182 embodying the principles of that shown in Figure 15 could be configured for more (or fewer) doses or drugs or for different calendar periods, for example weekly or monthly packs rather than daily. Nor is the card configuration essential, for example, a multi-drug container could be in strip or roll or book form, or metal

2

14 Variations on the theme of a scheduled dosage package will
15 be apparent to those skilled in the art. If desired, the
16 package could be standardized as to the number of dosage
17 compartments, providing for example, a compartment for every
18 hour, with those compartments lying between desired dosage
19 times being obviously blank or never filled. A valuable
20 feature of such packaging, which could be embodied in a
21 single prescription package, is that by giving the
22 physician-prescriber some physical control over the
23 circumstances that exist when a patient is supplied with
24 drug therapy for remote administration, the prescriber gains
25 the freedom to adopt time-related dosage variations during
26 the course of therapy, without confusing the patient. In a

5 Other regimens could provide higher initial dosages to build
6 up blood drug levels, followed by lower maintenance dosages.

9 have been packaged into the bay 184 that is appropriately
0 identified by patient, time and date. More subtle or more

possibly resumed after a suitable interval, while another continues. Another useful technique to be able to

17 administer another, to provide a graduated switchover.
18 Changing anticonvulsant therapies from one drug to another

20

24 time-related dosages, with defaults or preferred selections
25 for what can be system-determined as the most probable or

[illegible]

2

1 device can include a movable scanner that advances in
2 relation to a package from one bay 184 to the next, scanning
3 relevant compartments in the bay, as time passes, or it can
4 comprise an array of photoelectric sensors registering with
5 individual compartments of the package, which are
6 electronically controlled and read in turn, as time passes.
7 Equivalent sensing systems will be apparent to those skilled
8 in the art.

9
10 A preferred embodiment of dosing indicator device
11 accommodates, within an aesthetically pleasing housing, a
12 multi-bay scheduled dosage package, a time-and-date clock, a
13 time-related sensor to detect the presence of a drug dosage
14 in the bays one or more alerting systems, associated
15 electronics which may include a microprocessor, and a power
16 supply, for example, a battery, ac connector or remote
17 drawdown source, or the like.

18
19 Such a dosing indicator device can be embodied as a motor-
20 driven single- or multi-drug dosage dispenser which, for
21 example, can house a tape, or strip-like and preferably
22 rolled, scheduled dosage package, having a time line along
23 the roll, and advances individual bays 184 containing one or
24 more dosages for a given dosage time, and presents a single
25 bay 184 (containing one or more dosages) for external
26 delivery and removal (for example by tearing) by the

1 patient, or patient's aid, in timed relationship to the
2 dosage time (a half hour before, perhaps) and triggers one
3 or more alerts if the bay 184 is not removed (a half hour
4 after, perhaps).

6 Preferably, each bay is accompanied by written information
7 as to the patient, time and date, each drug, and any
8 relevant dosing instructions. The individual compartments
9 of such a removable bay cannot readily be sensed for the
10 presence of individual pills. Clearly a sensor is required
11 for the presence of an externally exposed bay. The system
12 assumes that the pills in a removed bay will be ingested,
13 but this assumption may be wrong on occasion. More rigorous
14 patient compliance may be exacted by including in, or in
15 association with the device, a receptacle for an emptied bay
16 184 and triggering alert means if such emptied bay is not
17 received within a specified time interval. Emptied bays can
18 be retained within the receptacle. To deter deceit of the
19 receptacle it can read a time and date stamp, or other
20 unique identifier on bay 184.

22 A multipatient version of the drug dosage dispenser
23 described herein can also be provided for inpatient use in
24 medical or health care facilities, especially hospitals and
25 clinics. Such a multipatient version could comprise a
26 central dispensing station, located for example at a nurse's

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26 The system can also screen or review for other possible

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1 unintended adverse outcomes to the prescribed therapy, or
2 for special precautions regarding a prescribed drug's use.

3
4 Preferably, the system alerts the physician-user at the
5 point-of-care if they prescribe an offending agent, and
6 provides an alert and an opportunity to amend the
7 prescription before dispatching it for fulfillment.

8 Processing to screen for interactions may occur on the
9 user's point-of-care device or on the host computer facility
10 or remote computer system, or may be delegated elsewhere by
11 the host computer facility, and reported back to the
12 physician, online as an integral function of the
13 prescription process. Alternatively, interaction screening
14 may be run on pharmacy-related systems, and notification of
15 problems can be sent immediately to the user's point-of-care
16 device using e-mail or using procedures within the
17 prescription management application of the invention.

18 *Sub*
19 *1951* An allergies review can be conducted by checking system-
20 stored known allergies of patient Mary Harrington against
21 known pharmacokinetics and pharmacodynamics of the newly
22 prescribed drug, entered in prescribing zone 44, for any of
23 those allergies. Mary Harrington's allergy information is
24 preferably an adjunct to her patient record and is
25 downloaded to the user device from ^{the} host computer facility
26 when Mary Harrington is selected from the patient selection

1 screen of Figure 2. Drug allergenic proclivities are also
2 downloaded from one or another remote database employing the
3 host computer facility, under supervision of the inventive
4 prescription management system, but preferably at a later
5 point in the procedure, such as when a particular drug is
6 selected for posting to prescribing zone 44.

Sub
Q22 Alternatively, the requisite information can be downloaded
9 when the allergy review is conducted. Such allergy
10 screening can alternatively be effected when a new drug is
11 posted to Drug field 88. Either way, a positive system
12 finding, indicating a risk of allergic reaction to the newly
13 selected drug can activate a visual indicator or warning,
14 for example, Allergies button 52 may blink and, if desired,
15 an audible warning may sound alerting the physician to
16 reconsider their selection. Alternatively, or additionally,
17 an alert screen can tell the physician of an allergy if an
18 attempt is made to prescribe an offending drug. Such alerts
19 can be used to notify the physician of drug interactions^{can provide adverse}
20 treatment warnings or can alert them to non-compliance with
21 formulary recommendations, for example to the use of an
22 unnecessarily expensive drug, and may be accompanied by
23 suggestions for more appropriate alternative therapies.
24
25 Equivalent procedures can alert to possible drug
26 interactions and contraindications, referring to the

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[illegible]

The inventive prescription management system embodiment disclosed herein is designed flexibly to facilitate a physician's prescribing activities, to place helpful information at their fingertips and reduce manual look-up chores, while avoiding any authoritarian direction, mandate or constraint upon a physician's professional activities or judgement. Thus, while the system may attempt to provide intelligent options and exhaustive selection lists, options such as "other" are always available to permit the

1 prescriber complete freedom of choice, whether or not their
2 choice is known to system-available databases.
3
4 Optional system enhancements provide for enrichment of
5 external communications, for example prescriptions and e-
6 mail with what may be termed "electronic ink" messages
7 generated at the user device. "Electronic ink" refers to
8 notes or messages appended to external communications, or
9 transactions in the form of free text or voice annotations
10 for non-structured instructions, and the like. Voice
11 annotation is particularly convenient, as well as possibly
12 constituting unique user-identification and some currently
13 available low form factor user devices incorporate a
14 microphone, facilitating voice annotation.
15
16 Toward the end of prescribing flexibility, to avoid being
17 second-guessed by physician users, and to command their
18 respect and loyalty, the system should have access to, and
19 provide to its users fully comprehensive drug and patient
20 information so far as this is available. Comprehensive,
21 accurate and complete drug and patient information are
22 equally important for effective prescribing. It follows
23 that the drug and patient information source databases from
24 which the prescription management system draws, must be
25 maintained up to date, by appropriate network services.
26

1 It is the normal, challenging nature of highly qualified
2 professionals that those with the latest news, such as new
3 drug releases and approvals, will want immediately to test
4 the system for currency with the news.

5
6 The unique source-oriented information retrieval and
7 updating system described herein provides preferred means
8 for supporting the prescription management system of this
9 invention with an adequate infra-structure of data-retrieval
10 networks supplying a comprehensive array of up-to-date
11 prescribing information and patient-related data to the
12 point-of-care. Other suitable information data retrieval
13 and updating systems will be apparent to those skilled in
14 the art and can be linked to the system of the present
15 invention to provide allergy and interaction alerts,
16 formulary changes, new drug approvals, and to lock out or
17 warn against, the prescribing of inappropriate or recalled
18 drugs.

19
20 Drug and condition selection

21 Novel drug selection methods pursuant to the invention will
22 now be described with reference to Figures 4 to 11. The
23 condition list selection screen shown in Figure 4 appears
24 upon activation of Condition field 86 in the prescription
25 management screen of Figure 3, to enable a prescriber to
26 approach selection of a treatment drug by first specifying a

1 diagnosed condition. Alternatively, a drug may be directly
2 specified by drug name^(Fig. 2a), by activating Drug field 88, as will
3 be described in connection with Figure 9, after which the
4 prescriber selects a condition to specify the purpose of the
5 therapy^{block 111}. Such condition or drug selection screens can be
6 opened by similar condition or drug buttons in any other
7 relevant screen or application, for instance in a patient
8 encounter screen where the drug selection routines now to be
9 described with reference to Figures 4 to 11 can be used to
10 assist a physician to select or review treatment objectives
11 in a computer-assisted patient encounter.
12

13 Condition list selection

14 The condition list-selection screen of Figure 4, provides a
15 preliminary selection of a suitable condition list from
16 which a physician user can work to select a drug. As shown,
17 the screen comprises a Select Condition List title 110 and a
18 Condition List display header 112 beneath which the names of
19 Condition Lists 114 are grouped in a left-hand column. A
20 right-hand column beneath header 112 displays the conditions
21 116 of whichever condition list 114 is highlighted, or
22 otherwise selected. In this case the user's personal
23 condition list 114 has been highlighted and may be seen to
24 comprise a short list of commonly occurring problems that,
25 for example, a general practitioner might encounter.
26

3

19 Preferably, the system includes frequency counters to track
20 the conditions the user encounters with time, and the counts
21 obtained are used automatically to maintain or generate a
22 Dx-Personal list 114 for the user, which more closely
23 portrays patterns of conditions encountered in the user's
24 practice as time goes by. Base periods for reporting usage
25 may be varied, or user selected, to list conditions
26 encountered by frequency in, for example, the last year, the

4

12

:

1. The first step is to identify the problem or goal. This involves understanding the current situation and what needs to be achieved.

Any or all condition lists 114 can be automatically supplemented or maintained by the system as it receives data in the course of processing numerous prescriptions for one or more physician users. In addition to supplementation with user-originating data, preferred embodiments maintain user profiles on a host computer facility which continually refreshes the data at the user's device so that the user can use any device or share a device with other users.

In the **Select Condition** screen of Figure 5, the patient

condition 116 in the Dx Personal category shown comprise generalized groups of disease, some serious like diabetes and pneumonia, and others less so, for example rhinitis or sinusitis. More complex embodiments than the one shown here may categorize conditions into as many as four or five different columns of subcategories of condition according to disease pathology, therapy, personal knowledge and so on. Such condition categorization, as a preliminary to drug listing, provides a very powerful tool for physicians to view their prescribing options on screen and to organize them. Organization of drugs by lists of effectively treated patient conditions enables a user intelligently to access a large body of drug data selections. This approach provides multiple mapping so that the user can find a suitable drug or selection of drugs via different pathways according to their preferred work methods.

Different pathways to a drug via conditions organized in other ways, notably by body system, are illustrated in Figure 8, described hereinbelow. Direct pathways of drug selection using drug lists are illustrated with reference to Figures 9 and 10, described hereinbelow.

In the example shown in Figure 5, the user-physician has highlighted and selected a patient condition 116, namely, peptic ulcer disease (PUD)/gastritis, displaying, in the

9

21

26

1 costs by using volume purchasing to get preferred pricing on
2 selected drugs.

3

4 A major problem in fulfilling the cost-control objectives of
5 a managed care organization is that of informing a
6 prescribing physician as to which drugs are in the formulary
7 for a given patient. Noting that there are many different
8 formularies it is quite impractical for the average
9 physician to keep referencing different formularies for
10 every patient every time they write a prescription. The
11 aspect of the invention shown in Figures 6 through 11 helps
12 solve this problem by providing computer access of remote
13 databases containing the information and by presenting
14 available formulary drugs in a form which is easy for a
15 physician to use, reference and prescribe without enforcing
16 physician compliance with a formulary's treatment guidelines
17 and attempting to restrict a physician's exercise of their
18 professional judgment.

19

20 To the contrary, the system of this invention is designed to
21 empower a physician to make informed choices at the point of
22 care. The system fosters quality, cost-effective
23 prescribing. Physicians do not have to attempt to remember
24 drug formularies and formularies may be changed with instant
25 effect on all users without having physicians relearn the
26 formulary. Where formulary information is called across a

1 data-retrieval network, each time it is required, in
2 accordance with preferred embodiments of the invention, from
3 a remote source database, updates are automatically posted
4 across the network.

5
6 Nonformulary drugs may be substantially more expensive than
7 formulary drugs, or may not be covered by the patient's drug
8 benefits plan, and may require out-of-pocket payments by the
9 patient which circumstance may cause administrative problems
10 to the physician and be a burden to the patient. Worse
11 still, the patient may not have the prescription filled.

12
13 By including pharmacy-derived prescription fulfillment
14 information, a patient prescription history can indicate
15 whether a patient actually received a medication. The
16 physician can be alerted (by e-mail) if a patient has not
17 filled a prescription for a critical medication, for example
18 LASIX (Hoechst), prescribed for hypertension, enabling a
19 follow-up with the patient to be initiated.

20
21 ~~213/~~ Where formulary drugs are professionally acceptable to the
22 physician and of equivalent therapeutic effect to non-
23 formulary drugs, failure to use them is clearly undesirable.
24 This problem is overcome by the present invention. If the
25 physician is satisfied with the formulary drugs offered by
26 the prescription management system of this embodiment,

1 anyone may be selected and automatically posted to the novel
2 prescription described herein as will be described.

3
4 Prescribing non-formulary drugs

5 Should the physician know, for example, that cimetidine and
6 ranitidine, drugs in a similar class, have been tried and
7 found ineffective and that the condition is well beyond
8 these first line treatments, so that none of the formulary
9 drugs is suitable, then the physician can select other,
10 which selection displays a nonformulary drug list 122, under
11 nonformulating drug header 124, as shown in Figure 7. In
12 this case, the physician selects Sucralfate as being a non-
13 formulary drug in a different chemical category and having
14 somewhat different therapeutic properties from those
15 previously applied to treatment of this patient's symptoms.

16
17 Having made the decision to select Sucralfate, the physician
18 is informed by the system display shown in Figure 7 that
19 sucralfate is a nonformulary drug not on patient Mary
20 Harrington's prescription benefit management company's
21 schedule. With this timely notification in hand, the doctor
22 can, if appropriate, consult with a patient, explain the
23 reasons for his or her drug selection and gain the patient's
24 agreement to assuming the cost of the prescription, or
25 obtain authorization from the plan to cover the cost of this
26 prescription for this exceptional case. Physicians

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1 manifesting increasing compliance flowing from use of a
2 prescription management system according to this invention
3 can expect ready approval of a non-formulary drug on a
4 justified exceptional basis.

5
6 By tying a diagnosed condition to a prescribed drug and
7 requiring a condition to be recorded as a treatment
8 objective before a prescription is fulfilled, new drug
9 formularies can be created where prescribing of a drug is
10 qualified according to the condition treated. For example,
11 an expensive drug like captopril may be a first-line
12 formulary choice for an acute condition such as congestive
13 heart failure, but not a first-line choice, or may even be
14 excluded as non-formulary, if prescribed for a chronic
15 condition such as hypertension.

16
17 In practice, after the system learns the user's preferences,
18 most condition and drug selections will be quickly made from
19 the user's preferred or custom lists or from historically
20 derived patient lists of previously encountered conditions,
21 or previously prescribed drugs. The system adapts to the
22 prescribing user to enable rapid creation of routine
23 prescriptions. A minority of situations may call for less
24 obvious therapies or therapies with which the physician has
25 little or no experience. Physicians tend to be most
26 reluctant to prescribe new drugs. Responsible physicians

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1 The drug selection screen shown in Figure 8 offers, by way
2 of example, one route to selecting a new drug not on the
3 prescriber's short lists. Here, selection is condition
4 driven and proceeds with the selection of a condition list
5 114, Dx by Body System or Dx by Therapeutic Class, and then
6 locating a drug to treat that condition; or alternatively,
7 by directly selecting a drug via drug lists 115 Rx by
8 Therapeutic Class or Rx by Alpha. Displayed in Figure 8,
9 reading across the columns from left to right, are a list of
10 body systems 117 from which the prescriber has selected
11 Musculo-skeletal. In the next right column the system
12 displays a list of conditions 116 that might be displayed by
13 the musculo-skeletal system, of which nine are listed by way
14 of illustration. From these nine the prescriber has
15 selected Osteoarthritis. Osteoarthritis is posted to
16 Condition field 86 in prescribing zone 44 of prescription
17 creation screen 39 (Figure 3).

18
19 With a condition specified, selection proceeds to the
20 choosing of a drug to treat the condition of osteoarthritis.
21 Drug selection proceeds through a preliminary selection of
22 drug category, from a list of drug categories 119 in the
23 next column to the right, enabling the prescriber to choose
24 their therapeutic approach, in this case, as between
25 employing an analgesic, a narcotic, a NSAID (non-steroidal
26 anti-inflammatory drug) or a salicylate. A NSAID is chosen,

1 generating an extensive list of drugs 121 in the right most
2 column in Figure 8, from which the prescriber can make their
3 final selection which will be posted to Drug field 88 in the
4 prescription creation screen 39 (Fig. 3).

5
6 The complexity of the prescribing process is graphically
7 illustrated in Figure 8. Even after narrowing the field
8 down to a specific class of drugs, NSAIDS, for treating a
9 particular symptom, osteoarthritis, there are still of the
10 order of fifty drugs from which the prescriber makes a final
11 selection.

14 Direct drug selection

15 Prescribers often know what drug they want to prescribe and
16 will wish to access it very quickly, and may not use the
17 system if they are unable to do so. This goal can be
18 reached with user-adaptive personal drug lists organized to
19 default to a prescriber's preferred choices, as described
20 herein.

21
22 One preferred user-adaptive approach to providing a quick-
23 prescribing pathway to a prescription is for the system to
24 process the user's personal drug list, to highlight, or
25 short-list or otherwise present those drugs on the personal
26 list that are appropriate therapy for any of the patient's

1 121 in the next column. This approach can quickly locate a
2 target drug when the physician knows it by name. Here
3 Cefixime has been selected and the system calls for, and
4 requires, the prescriber to enter a condition before
5 proceeding to quantification of the prescription. In the
6 next column the system lists conditions that the user has
7 previously treated with Cefixime, highlighting the most
8 recent condition so treated, or the system may display a
9 previous condition of this patient that was treated with
10 cefixime, not necessarily by the current user. If the
11 physician wishes to attack some other condition with
12 cefixime, such other condition may be selected from the last
13 righthand column, activated by "other".

14 The diversity of conditions treatable with cefixime
15 illustrates the potential for outcome studies based upon
16 widespread use of systems according to the invention to
17 refine definitions of the therapeutic scope of individual
18 therapeutic agents by collecting data on effective new
19 applications and on precautions, interactions and side
20 effects.

21
22 Some advantages of condition-specified drug prescribing

23 Being abundantly served at the point of care with relevant
24 prescribing information at the critical moment of decision,
25 the physician can eliminate many subsequent problems or
26 difficulties which may lead to unnecessary paperwork, or

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1 surprised, annoyed or non-compliant patients, and to
2 unnecessary phone calls between pharmacist and physician
3 when a patient learns only at the pharmacy that their
4 prescription is non-formulary. The system can eliminate
5 much unnecessary "phone tag" between pharmacies and
6 physicians. Improved physician and patient compliance with
7 preferred guidelines will reduce the cost of care and
8 increase the quality of care.

9 *as*
10 The availability, by means of the invention, of vital drug
11 selection information, categorized by therapeutic condition
12 and denoted as formulary or not, for the patient in
13 question, rapidly assembled, preferably from remote source
14 data, and conveniently presented to a physician for flexible
15 use in their own personal work flow, greatly enhances
16 prescribing practices, fosters cost containment and eases
17 the administrative burdens that fall on heavily prescribing
18 physicians. It enables informed choice at the point of care
19 leading to a decrease in adverse outcomes of therapeutic
20 choices.

21
22 Naturally the prescription management system of the
23 invention can provide a variety of printed reports and other
24 data outputs of any facet of the described operations. In
25 some cases, these reports can be enhanced to provide
26 entirely new products for example a dosing schedule such as

1 that described with reference to Figure 15, and shipping
2 schedules or split prescriptions divided according to
3 suppliers requirements.

4
5 Current and historical reports can, subject to the access
6 controls described herein, be patient-specific, prescriber-
7 specific or organization-specific and can be aggregated
8 across various groups, pools, geographical regions,
9 conditions, drugs, or time periods or combinations of any of
10 the foregoing to provide a valuable data resource to health
11 care providers, patients, managed care organizations,
12 government agencies and others.

13
14 Further to enhance the prescribing decision process,
15 additional features can be included on screens such as
16 Figure 7, for example drug pricing information, employing
17 actual wholesale or retail pricing, or comparative pricing
18 or on another manner of drug pricing or grouping, such as a
19 comparative scale or price rating system, or relative
20 pricing based on actual prescription benefit management
21 company contracts. Such pricing information can greatly
22 influence M.D. decision-making, improving formulary
23 compliance and reducing overall drug costs, without
24 restricting a physician's choices.

25
26 A powerful optional feature of the invention is shown in

26
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1 exemplary fashion by the drug evaluation screen depicted in
2 Figure 11. After a physician selects a drug from one of the ^{block 121}
3 screens of Figures 7 to 10, the system can optionally scan a
4 drug preference database of preferred drug treatments for an
5 evaluation of the merits of the selected drug in treating ⁵¹
6 the condition. ^{in general and for this selected patient} The drug preference database may be remote
7 and may be maintained, for example, by a managed care
8 organization, HMO, or prescription benefits management
9 company. As the Figure 11 example shows (which example
10 employs different condition and drug selections from those
11 used in Figures 6 and 7) one possible result of the database
12 scan may be an on-screen report with an alert message, in
13 header 126 advising the physician that the selected drug is
14 "Not a first line drug" for treating the selected condition.
15 As a helpful suggestion to the physician the system can also
16 offer alternative drugs, from listings in the drug
17 preference database, as being more meritorious for the
18 treatment of the condition in question (pursuant to the
19 maintaining benefit company's standards or, preferably, to
20 objective literature reports).

21
22 To this end, the drug selection evaluation ^{block 69} screen of Figure
23 11 comprises an explanatory box 128 elucidating header 126;
24 an alternative drug selection menu 130; and at the bottom of
25 the screen, three action buttons; for example, Tx Guidelines
26 132 to access treatment information about the alternative

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;

Although described as a self-contained system, it will be

1 appreciated that functions such as the identification and
2 listing of drugs via conditions treated, and patient
3 prescription histories will have value in other systems, for
4 example, patient encounter management systems, and may be
5 accessed directly from such systems via a prescribing
6 information button.

7
8 As well as compensating for error or lack of information on
9 the physician-user's part, the prescription review system
10 exemplified in Figure 11 has great value as an educational
11 tool. Physicians can be subtly trained to improve their
12 drug selection behavior. By using the system aggressively
13 and exploring its information resources, as they are
14 encouraged to do by the system's prompts and alerts,
15 physician prescribers effectively receive education and
16 training at the point of care. Improvements in drug therapy
17 are subtle and complex and it is often difficult, even for
18 the most conscientious of physicians, to be abreast of
19 developments in any more than one narrow field of medicine.
20 It is just as difficult for purveyors of new drugs to break
21 in to a physician's packed work schedule to educate them as
22 to the merits of a valuable new drug.

23
24 More than one alternative drug may be offered. Also in an
25 optional embodiment not shown, the physician user may choose
26 to display a screen of drug information regarding the

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1 alternative drug or any other drug. After confirming a drug
2 selection the system can review the patient's history in
3 relation to the selected drug and alert the physician to any
4 relevant allergies, one-on-one drug interactions or, if
5 appropriate, multiple drug interactions.

6
7 Often, when new drug information is presented, a physician
8 is unable to consider it, yet when the information is
9 needed, or could be used, for example at the point-of-care,
10 when creating a prescription, valuable new drug information
11 may be unavailable or forgotten. This invention solves that
12 problem by presenting new drug information in a timely
13 manner at the moment when it is most needed and a physician
14 is most interested in considering it, namely at the time of
15 writing a prescription. It gives a benefit management
16 company the opportunity to influence a physician's choice at
17 the most influential moment, during the prescribing
18 decision.

19
20 User-adaptive drug formulary compliance

21 Conventional formulary guidelines specify one or more
22 substantial lists of preferred drug therapies. Many of
23 these drugs will be unfamiliar to most prescribers who will
24 therefore be reluctant to prescribe them. Natural
25 professional prudence makes most physicians extremely
26 cautious about specifying powerful agents for therapeutic

1 goals when they have little or no prior experience with the
2 agents but will be responsible for the outcome of the
3 treatment.

Sub⁴
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4 The system of the invention can provide a novel approach to
5 drug formulary management whereby prescriber-centric
6 formularies can be established. By means of the system,
7 drug formulary guidelines effectively adapt to the user's
8 prescribing patterns or ^{preferences} can be followed effortlessly by the
9 prescriber. This desirable prescriber-centricity can be
10 obtained by giving priority to the prescriber's personal or
11 custom lists or, better still if they are a subset of these,
12 to the patient's history lists, and system-identifying
13 patient-formulary preferences on those lists for easy final
14 picking by the prescriber. Where the prescriber is
15 selecting a drug providing effective therapy for a just-
16 specified condition, the above procedure may often clearly
17 identify a single drug meeting all requirements or may
18 result in a short list of a very small number of drugs for
19 final selection. Where no drug is listed as meeting all
20 requirements, the system may so alert the user and suggest
21 formulary drugs not on the doctor-specific lists or ask the
22 user whether they wish to review appropriate non-formulary
23 drugs from their personal or custom lists.
24
25
26

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Patient's prescription history

Figure 12 shows a prior prescription information screen which can be displayed by double clicking the prescription display line or activating RX History button 54 in a screen zone such as prescription history zone 43 of prescription creation screen 39 shown in Figure 3. The embodiment of screen shown in Figure 12 provides a simple passive information display, comprising an information box 138, a close button 140 and a scroll bar 142 for scrolling or browsing a library of prescription histories. The displayed prior prescription information in box 138 comprises, for the selected prescription, the condition for which the drug was prescribed, the drug name, date of prescription, dates of any renewals and the name, phone number and any other appropriate identification of the prescribing physician, in this case it is the user physician, and any other useful details that may not be strictly prescribing information, including appended free text, voice annotations or other electronic ink. Where an "N" indication appears in the Mine column 76 on the prescription history line in Figure 3, the name of another physician who authored the relevant prescription will appear in Figure 12.

In addition to conveniently presenting useful historical prescription-related details, powerful optional features, for example, direct E-Mail communication with the physician

whose name is displayed (or with some other physician) can be activated from the prescription information screen of Figure 12 or other suitable screen, can be included in the prescription management system of the invention. Such options enable physicians to send an inquiry to, and perhaps retrieve relevant records directly from another physician such as a previous prescriber to the patient, or a referring physician. The invention facilitates the execution of such information transports during the user-physician's encounter with their patient. The screen of Figure 12 could additionally have an Auto Dial button and be linked to other modes of communication to facilitate a direct connection to the physician of interest. Additional options include a display of historical dosage information and an ability to page through all prior prescriptions or all prescriptions for a given patient, a given prescriber, a given condition, a given therapeutic class, and so on, recapping some of the functionality of the Figure 3 prescription creation screen 39.

A further optional feature of the invention is shown in the patient problem or condition screen of Figure 13, openable, for example, from Problem button 50, Figure 3, which tracks, as indicated by the field headers 144-156 extending across the screen, a history of the patient's problems and records diagnostic determinations regarding individual problems.

:

:

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1 list in Diagnosing Physician field 150 (which the system
2 will default to the current user); inserts the date the
3 problem was added in Date field 152; inserts the name of the
4 physician determining the problem is resolved or no longer
5 active in Resolving Physician field 154; and inserts the
6 date of resolution in Date field 156. Thus changes to the
7 patient record are stamped with the name and date of the
8 responsible physician to provide an audit trail. A
9 physician identifier can be added if desired.

10
11 Problems that no longer manifest themselves to the patient
12 or physician can be indicated as not active in Act field
13 148. The problem list can be sorted by header selection and
14 preferably presents active problems at the top of the list
15 by default.

16
17 Such a system-maintained problem list provides an easy and
18 convenient reference to the patient's history of conditions
19 or problems and of the duration and currency of such
20 problems and constitutes a valuable case management tool for
21 physicians. The problem list is automatically supplemented
22 during the prescribing process with the latest prescriber's
23 latest observations and diagnoses, as indicated by selection
24 of one or more conditions for posting to a new prescription.

25 A9

26 Where a patient complains of an old problem a quick

1 prescription creation routine comprises selecting the
2 problem from the Dx-Patient list 114, then selecting a drug
3 from a system-generated pick list of drugs providing
4 appropriate therapy for that condition. The pick list is
5 preferably drawn from the doctor's personal list and is
6 either compliant with the patient's formulary guidelines, or
7 indicates those guidelines, for example by inverse video,
8 highlighting or the like, and also includes a selection of
9 "other" to access drugs not on the prescriber's personal
10 list. Such a quick prescription routine enables the most
11 routine situations to be promptly handled, yet permits the
12 physician to expand their prescribing horizons and does not
13 merely require selection of the same drug as was used
14 previously. Quick treatment substitutions are made possible
15 by the system's presentation of available alternative
16 therapies enabling the prescriber easily to see what
17 alternatives are available and to explore those with which
18 they are unfamiliar.

19
20 Also the problems or conditions on this list can be
21 automatically posted to a patient problem list 114 to appear
22 as an additional "Dx" list in screens such as those shown in
23 Figures 4-10, to provide quick selection or review of a
24 patient's historical conditions. Preferably, such a Dx-
25 Patient list 114 changes automatically when another patient
26 is selected.

1 As various system-using physicians, laboratories and the
2 like encounter the patient or provide services to the
3 patient, they become original sources for new record
4 elements memorializing their encounter with the patient or
5 the patient's attributes. The patient's history
6 accumulates, and the system compiles, on demand, a
7 cumulative virtual patient record including all newly
8 created record elements. This current patient history
9 record is promptly available to any authorized physician
10 user on the network. In an ideal world, all relevant
11 encounters are captured so that the patient's record is
12 comprehensive or complete.

13
14 The value to a patient's care givers, of an instantly
15 available, comprehensive patient record cumulatively
16 reflecting all current and recent medications and
17 conditions, is immense. Its availability to emergency
18 personnel may be life saving.

19
20 The problem list screen of Figure 13 is accessed from
21 prescription creation screen 39 (Figure 3) by pressing
22 button 50. Selecting an OK button 158 or Cancel button
23 160, the problem list returns to prescription creation
24 screen 39 (Figure 3). Change Status button toggles the
25 highlighted Act entry between "Y" and "N", and records a
26 date and physician name with any status change. Add button

1 164 enables a physician user to add a new condition to the
2 list, using condition selection pick lists, as previously
3 described. This routine may be used to note problems for
4 which there is no specific prescription given, e.g. obesity
5 or senile dementia.

6
7 Where the inventive prescription management system is
8 applied to statistical data collection for outcome studies,
9 it is preferable to supplement the patient record with a
10 range of relevant personnel data, to the extent that this is
11 available, for example drug abuse behavior, smoking and
12 habitual eating or drinking behavior, dietary habits,
13 marital and family status, pregnancies, ethnicity,
14 environmental factors, and so on. The system provides an
15 excellent means for tracking these factors and their changes
16 as they may pertain to an individual's health. For example,
17 data fields could be added to record any of the foregoing
18 data and the data could be updated by medical or
19 administrative personnel in preparation for a patient-
20 physician encounter.

21
22 Of particular significance to outcome studies will be death
23 certificate information, and preferably this information is
24 added to the patient problem record of Figure 13, as
25 appropriate.

26

1 More complex embodiments of the invention can integrate
2 applications for prescription management with equivalent
3 applications for diagnostic tests, laboratory analyses, and
4 radiological studies to provide a more comprehensive patient
5 history viewable in multiple screens. Of particular value
6 in such an integrated presentation are laboratory results
7 providing drug dosing levels, renal and liver function tests
8 that provide important indications as to appropriate dosing,
9 and so on.

10
11 Figure 14 shows a manually maintainable problem record
12 maintenance screen, for physician use, which can be accessed
13 for example from the Doctor's lists button 24 in the system
14 entry screen of Figure 1. This screen enables a doctor or
15 physician manually to maintain their own personal customized
16 prescription, diagnosis, allergy or other useful lists, to
17 supplement the automatically maintained system lists. If
18 desired, problems the doctor's patients have experienced
19 previously can be system-added to the list, for example when
20 a patient is selected. These personalized lists or profiles
21 are posted to the network where the system can retrieve them
22 to any user interface device via a host computer facility,
23 subject to appropriate password protection or the like.
24 Relying upon such centrally stored personalized profile
25 files, the system can present a customized, personal
26 appearance, with familiar configurations, attuned to the

1 user's work habits, at any geographical location from which
2 the network can be accessed.

3
4 The problem record maintenance screen of Figure 14 comprises
5 a Problem List box 166, a List Type box 168 and a Problems
6 box 170 displaying a comprehensive, or preferably exhaustive
7 list of problems which can be selected and transferred to
8 the network and the physician's problem list by pressing
9 update button 172. Highlighted entries can be removed from
10 the Problem List 166 by pressing delete button 174. Save
11 button 176 and Exit button 178 perform the usual functions,
12 and preferably provide options to cancel changes, and the
13 like. Data entry box 180 permits an unlisted condition to
14 be keyed in, or otherwise entered character-by-character and
15 paging buttons 142 move between lists.

16
17 Archiving

18 Given the medical, commercial and legal significance of the
19 transactions executed and the data generated by use of the
20 system of the invention described herein, as well as the
21 value of that information to the patient, the physician and
22 many other organizations, maintenance of accurate historical
23 records, or archiving, is desirable, or essential, and
24 preferred embodiments of the invention provide archiving at
25 a host computer facility 106.

26

1 Data storage burdens attendant upon long-term archiving are
2 substantially relieved by using virtual patient records, as
3 described herein. Pursuant to the principles relating to
4 the use of virtual patient records dynamically created from
5 source data record elements, the invention prefers to
6 archive such data as will enable a full and accurate record
7 of the past to be regenerated from diverse sources, rather
8 than recording the past verbatim. Date and time stamped
9 record elements allow recreation of a virtual patient record
10 at any point in time.

11
12 Preferably, the data logged into archives comprise all data
13 relevant to a patient's diagnosis and therapies, data
14 relevant to the user's prescribing activities, including the
15 prescriber's relevant electronic communications ("e-mail")
16 with third parties (pharmacies, laboratories, other health
17 care providers, or potential providers, to the patient, and
18 so on) and access audit data as to parties accessing the
19 patient's or prescriber's personal data.

20 21 System-support infrastructure

22 Referring to Figure 16, the lefthand side of the diagram
23 shows an arrangement of services and devices that provide a
24 downstream flow of data and communications resources to
25 users of the prescription management, or other system
26 described herein. The righthand side shows sources from

1 which desired data and data elements may be drawn and
2 pathways for those data to reach the user, the flow being
3 marshalled by a centrally depicted host computer.

4
5 Shown schematically in Figure 16, are a number of user
6 interface devices 200 and a desktop computer 201
7 communicating via any of a variety of communication services
8 202, through a gateway-router 204 with a host computer
9 facility 206. The drawing depicts schematically how a group
10 or pool of users working with interface devices 200 or
11 computers 201, running the prescription management software
12 of this invention, can be serviced by host computer facility
13 206. Those skilled in the art will appreciate that the
14 schematic layout shown in Figure 16 is described in terms of
15 its logical architecture and that the actual physical
16 disposition of elements may be quite different.

17
18 In addition to coordinating system-related communications,
19 especially retrieval of source data from remote databases,
20 gateway-router 204 can manage supplementary services such
21 for example as a paging service 208 or any other relevant
22 desired function.

23
24 Interface devices 200 are depicted as small form factor,
25 handheld devices, or PDA's, communicating wirelessly over a
26 WAN, a proprietary wireless service, or a cellular digital

1 packet data service, or the like. Desktop computer 201,
2 which may be a portable, notebook or other higher form
3 factor computer, connected to communications gateway-router
4 204 via a local area network labeled LAN₁, which connection
5 could equally well be via modem, infra-red, wireless or the
6 like, depending upon the circumstances. Any suitable
7 network may be used, depending upon the user's equipment and
8 the location of desired resources. Wired or wireless, local
9 or wide area networks, or mixed networks, are suitable.

10
11 Routing to the appropriate service and other communications
12 technicalities are coordinated by communications gateway-
13 router 204 which is networked or otherwise connected with
14 host computer facility 206.

15
16 Other prescribers (or other professionals in different
17 environments) may use different methods to communicate with
18 host computer facility 206 using a two-way digital data
19 communication system across a network.

20
21 Still other users may be supported by other host computer
22 facilities communicating in their turn with host computer
23 facility 206 using appropriate network services and
24 providing communication links or pathways between such other
25 users and physician users supported by host computer
26 facility 206. Such organizations employing one or more

each of both users and host computer facilities are intended by references herein to "network" or the "network".

Communication services 202 can be any service providing effective two-way data transfer between users 200 and host computer facility 206. As labeled, some possible communication services 202 are wired local area networks "LAN₁...LAN_n", wireless local area networks "WLAN₁...WLAN_n" and proprietary radio frequency packet data networks, such as ARDIS and RAM (trademarks of their respective proprietors), cellular digital packet data networks "CDPD₁...CDPD_n" and so on.

Not shown is a wire telephone connection between a user device 200 and communications gateway-router 204. This is of course a possible embodiment of the invention and it is also, to be understood, local area networks LAN_n, could comprise a single desktop computer or a facility-based networked system of multiple desktop, or other computers.

Communications gateway-router 204 manages communications through these various media services and provides consistent interfaces to users at devices 200 and to host computer facility 206, regardless of which communication service 202 is used.

8

18

19 Host computer facility 206 provides intelligent network
20 services to user devices 200 and 201 and may support
21 ancillary services, especially for example, as described
22 hereinbefore, patient-directed data access control software.
23 Prescriber-directed data access control software or
24 organization-directed data access control software could
25 also run in an application separated from the prescription
26 management system, but is preferably integrated therewith as

1 a component of a user initialization routine.

2

3 Conveniently, patient interface components of the patient-
4 directed data access control software are run at separate
5 stations from the point-of-care locations used by
6 prescribers and are located, for example, in administrative
7 or reception areas of health care facilities or managed care
8 organizations. Here, data access rights may be read off a
9 patient's data access control card, and such cards may be
10 issued, under control of software supplied by, and in
11 communication with host computer facility 206.

12

13 The level of software and data resident on interfaces
14 devices 200 can be varied according to their physical
15 capabilities and user or system administrator preferences.
16 At a minimum, and for device redundancy, interface devices
17 200 need have resident neither files nor software, beyond
18 what is supplied with the device off the shelf.

19

20 So long as the user interface device has an operating system
21 and is communications-equipped, they may establish
22 communication with host computer facility 206, using a
23 separately supplied electronic address for that facility and
24 may upload necessary program components and data files,
25 including such personalized user profiles as have been
26 established by the user's prior experience with the system

1 and which have been stored at the host computer facility
2 206, are called from a remote host computer facility
3 supporting other users.
4

5 Neither such program components, nor data, need be stored on
6 the interface device 200 but, where the device 200 has
7 adequate storage capacity, it will be more convenient and
8 faster-loading for a user to maintain configuration and user
9 profile files, along with limited amounts of relevant drug,
10 and possibly patient data, on the user's local interface
11 device 200. Preferably, however basic system access
12 software is required to be installed on the user device
13 before system resources can be accessed. Such basic system
14 access software can be activatable after reported loss or
15 theft to disable system access capabilities and to render
16 any stored proprietary data inaccessible to unauthorized
17 users.
18

19 Host computer facility

20 Host computer facility 206 provides full software support
21 for user interface devices 200 and maintains complete
22 program files for the prescription management system along
23 with e-mail services and any other non-personal applications
24 that may be needed by users of devices 200 beyond the basic
25 operating systems and utilities, and the like, with which
26 the devices are originally equipped.

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1 Host computer facility 206 maintains databases of patient
2 information for patients encountered or whose records have
3 previously been viewed by users of devices 200 in response
4 to calls sent via host computer facility 206, (and logged by
5 it for audit purposes) but, in keeping with the preferred
6 practice of the present invention, host computer facility
7 206 does not maintain patient records in permanent storage.
8 It could however be used to maintain patient record
9 components that are source components to users of devices
10 200 for which this particular host facility 206 is, at it
11 were, their "home" facility.

12
13 Important functions maintained by the host computer facility
14 206 are information locator databases and advanced directory
15 and routing services, including the following:

- 16 i) a user device and system registry enabling
17 communications to be routed to the target user;
18 ii) a patient information directory service enabling
19 access the system to access remote databases to
20 retrieve patient record components for compilation
21 of virtual patient records as described above;
22 iii) archiving of transaction logs and records, and of
23 audit logs;
24 iv) patient drug formularies and formulary guidelines
25 or locators to access same;
26 v) libraries of alerts and other system displayed

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1 them to users for assembly into a virtual patient record by
2 an interface device 200 or 201, in response to the user's
3 call for that record.

4
5 Host facility 206 can reach out nationally, or
6 internationally, for example across the INTERNET (trademark)
7 to multiple remote databases such as remote databases 210
8 shown on the right hand side of Figure 16, to provide to
9 users of interface devices 200 data resources beyond (and
10 potentially more current than) those available from direct
11 storage in the device or at the host facility.

12
13 Communications

14 Communication between host computer facility 206 and remote
15 databases 210 will usually be via wire lines such as
16 telephone, or local or wide area network communication via
17 copper line, or optical fiber, or any other suitable
18 communication medium. Clearly, host computer facility 206
19 can access any remote third party database with which
20 appropriate arrangements have been made, or can be made on
21 line, and some possible source databases for patient records
22 components are labeled as ⁶⁶ "HMO's, Hospitals Insurance, Drug
23 Benefit Cos, Pharmacies, Labs and Independent Physicians".
24 Drug information may be additionally sourced from
25 pharmaceutical companies' research centers, reference
26 libraries, or publishers and the like.

1 One or more pools of users of devices 200 and computers 201
2 constitute a valuable professional audience and the system
3 provides a valuable means enabling such third party database
4 proprietors to become data publishers and electronically
5 publish or post their databases or on the network to reach
6 that audience.

7
8 Using recognizable common record element identifiers, for
9 example patient identification numbers or drug identifiers,
10 host computer facility 206 forages across available networks
11 for similarly identified record elements to retrieve.
12 Employing its information directory services as locators,
13 host computer facility can retrieve a variety of data
14 including patient-specific data, application-specific data
15 (users preferences and the like), organization-specific data
16 (formulary guidelines, for example) and general drug or
17 prescribing data, e.g. from MEDLINE.

18
19 To assist with compatibility problems with the legacy
20 systems operating at remote databases 210 and to avoid heavy
21 volumes of user calls, via the systems of the present
22 invention, interfering with or slowing down the daily
23 operations at the proprietary facilities supporting the
24 remote data bases 210, this embodiment of the invention
25 provides, at each of a limited number of remote databases
26 210 known to be a significant source of patient record

elements, a dedicated data warehouse 212. Data warehouses 212 can be real or functional, depicting either actual physical embodiments of system-dedicated services located at the facilities of remote databases 210, or logical functions executed at the host computer facility 206.

Data warehouses 212, host computer facility 206, communications router-gateway 204 and communications services 204 are components of a conceptual integrating network 214 which brings users of devices 200 and 201 transparent access together with the resources available at remote databases 210, and preferably gives those users a seamless appearance, as though data stored piecemeal at multiple remote databases 212 were directly available from a single file across a local area network.

To facilitate connection with heterogenous databases, and to give their proprietors fluent access across the network, it is preferred that the system provides uniform application programming interfaces, remote API's 216 for use by third party developers. Compatible user API's 218 on the downstream side provide similar standardized connectivity with user devices 200 and 201.

Integrating network 214 and API's 216 and 218 permit easy system integration, allow third parties to develop end-to-

:

:

Each data warehouse 212 maintains replicated copies of relevant data sets obtained by read-only access of remote databases 210, which data sets are maintained synchronously with updated source data at remote databases 210, or are periodically refreshed therefrom, preferably at frequent intervals. Data warehouses 212 can also provide search and retrieval facilities and, in particular, provide protocol interchange and reformatting capabilities to reformat or otherwise standardize data and communications across network 214, for any application to use. Preferably, to facilitate compliance with the desired auditability of the transactions and data accesses of preferred embodiments of the invention, data warehouses 212 screen data incoming from associated data warehouses 210 for date-stamping, and preferably, also time-stamping, of individual received data or record elements, and reject those that lack such stamps. Preferably also, the date stamp indicates origination, creation or updating of the data element, rather than being merely a date of entry of the data element into data warehouse 212.

1 Source data generated by point-of-care or other transactions
2 at user interface devices 200 or computers 201, can be
3 directly posted to remote databases 210 across network 214
4 which bears two-way traffic. As will be apparent from the
5 disclosure herein, remote databases also include data from
6 other places, for example pharmacies, laboratories and
7 testing facilities.

8
9 Communications gateway-router 204 also maintains a
10 physician-device directory providing routing or access
11 information needed to establish communication protocols with
12 each individual physician. This device directory service
13 can maintain an electronic address, a device identifier or
14 device configuration, operating system information and user
15 device communications protocols for each user device
16 supported by the gateway-router. User ID's can be listed
17 separately and in preferred embodiments are accompanied by a
18 prioritized listing of one or more device addresses where
19 the user may be accessed.

20
21 Other temporary or permanent update means are provided to
22 enable a user to access the host computer facility from more
23 than one device, preferably using an address that is device-
24 independent.

25
26 It will be understood that an individual host compu'

1 facility 206 can serve one group of users that may, for
2 example, be defined geographically and may number from, for
3 example, as low as 10 or 20 users in the early days of
4 establishment of the facility to hundreds and thousands as
5 the facility matures. To service more users or to service
6 users in other geographical areas, additional host computer
7 facilities 206 can be established as centralized or
8 regionally distributed hubs. Such additional host computer
9 facilities 206 will, in all likelihood, access many of the
10 same remote databases 210. Preferably, switching or
11 rerouting means are provided to optimize data traffic loads
12 between multiple host computer facilities 206.

13
14 It will also be understood that a national or international
15 network can be created by establishing a sufficient number
16 of host computer facilities 206 in strategic locations, each
17 serving a local client base of, for example campus or
18 regional users, with interface devices 200.

19
20 Summary

*Sub
U 281*
21 The foregoing description has emphasized an approach to
22 therapy prescribing which records an association between a
23 therapeutic agent (drug) and a condition or problem targeted
24 for resolution or amelioration by the prescribed therapeutic
25 agent. Significant benefits derive from organizing known
26 therapeutic agents according to conditions for which they

1 are known to be effective, and emphasis has been placed
2 herein on a drug selection and specification which begins
3 with selection of a problem or condition to be treated,
4 because this is ^{believe to} be an appealing and beneficial approach in
5 many circumstances. Frequently however, the physician may
6 know exactly what drug they wish to prescribe, in which case
7 they can proceed to a direct drug entry screen, and then
8 ^{specifying} ~~specify~~ the condition targeted by the prescribed treatment. ^{cf}

10 While emphasis has also been placed in the principle
11 examples on the prescription of drugs, it will be
12 appreciated that the invention can be beneficially applied
13 to the specification of other therapies and technical
14 remedies for example to the specification of surgical
15 procedures, physical therapies and diagnostic testing.

17 Preferred embodiments of the invention include quick and
18 easy routines for directly posting a drug to a prescription,
19 without prior condition selection, such routines preferably
20 being by-passed. In order to gain the subsequent
21 historical review and outcome study benefits described
22 herein, it is preferred to provide for inclusion of a
23 treatment objective of the prescribed drug in the
24 prescription record before completion of the prescription.
25 The treatment objective can be rapidly selected from a
26 system-supplied list of a patient's existing or historical

1 conditions, or through powerful system-aided selection of a
2 new condition. While a default patient condition or
3 problem may be suggested by the system for a particular
4 prescribed drug, it is preferred that such default be
5 actively confirmed by the prescribing user before being
6 accepted by the system.

7
8 To accommodate direct prescribing by drug name, Drug field
9 88 of the prescription creation screen of Figure 3, can open
10 a personalized or customized user-activatable drug list, or
11 proceed to comprehensive system drug lists to enable rapid
12 specification of familiar or unfamiliar drugs prior to
13 condition selection. Drug dosage selection then proceeds as
14 described above. Before leaving prescribing zone 44 of the
15 prescription creation screen 39 the system can require an
16 appropriate entry to be made in Condition field 86.

17
18 Other preferred embodiments enable the patient, the
19 prescribing physician and the relevant organization to
20 control the flow of their own data by predetermining access
21 rights to that data. Every transaction can be stamped with
22 a patient identifier, a prescriber identifier and, if
23 appropriate, an organization identifier, as well as with the
24 date and time of day.

25
26 Emphasis on preferred, historical or customized short lists

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1 of drugs and conditions enables an attractive working
2 environment to be provided even on relatively low power
3 PDA's. Short list data may be maintained on the user device
4 providing rapid responses in the user's most common
5 prescribing situations. Less common situations entail calls
6 to the host computer facility, in which circumstances delays
7 of a few seconds while data is retrieved from the network
8 are quite acceptable.

9
10 System requirements

11 User software components of a currently preferred embodiment
12 of prescription management system described herein are
13 designed to run under an operating system that preferably
14 supports a full or modified version of MS-DOS® (trademark,
15 Microsoft Corporation) WINDOWS™ (Microsoft Corporation) or
16 other systems with user-friendly graphical interfaces, for
17 example Apple Computer Co.'s MACINTOSH (trademark) or NEWTON
18 (trademark) operating systems and General Magic's MAGIC CAP
19 operating system. Other graphical environments can be used
20 or are being developed and other embodiments of the
21 invention may be suitably modified to optimize the
22 application to take advantage of the unique characteristics
23 of each such operating system environment.

24
25 The programming language used to write system software
26 depends upon the environment of the various system

1 components. In their present stage of development, some
2 handheld PDA's require applications to be written with the
3 tools provided by their respective operating systems such as
4 NEWTON or MAGIC CAP (trademarks). For other devices such as
5 those supporting Microsoft's WINDOWS (trademark) operating
6 system, including some PDA's, a range of languages can be
7 used including for example, popular programming languages
8 such as Microsoft Corporation's "C" or Borland
9 International's "C++". For Apple Computer's MACINTOSH
10 (TRADEMARK)-based systems, languages such as THINK
11 (TRADEMARK) are appropriate.

12
13 The system is particularly advantageous when implemented on
14 any of a variety of portable computer stations especially
15 handheld units such as personal digital assistants and other
16 personal information communicators equipped with wireless
17 communicators. A preferred embodiment for mobile
18 professionals comprises such a handheld unit with two-way
19 radio or infrared communication facilities. Some such
20 devices are referenced in a "BUYER'S GUIDE: PERSONAL DIGITAL
21 ASSISTANTS" PC WEEK August 29, 1994, pages 89 and 94 the
22 disclosure of which is hereby incorporated herein by
23 reference thereto.

24
25 For compatibility with the currently rather limited
26 performance specifications of such desirable handheld

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1 devices the prescription management system of the invention
2 is preferably designed to minimize the storage and
3 processing requirements placed on the user's terminal and to
4 off-load storage and processing to host computer facilities.
5 Thus, the system's support architecture aims to supply to
6 the user terminal only essential data required for screen
7 displays and other user functions, on an as-needed basis,
8 while the network stores applications and data files, for
9 example at the host computer facility.

10
11 Modified Embodiments of the Invention

12 While the invention has been described with a reference to a
13 particularly valuable embodiment of a prescription
14 management system, it will be understood by those skilled in
15 the art that alternative embodiments of the invention can
16 bring valuable benefits in their respective fields where
17 informed choice is desirable and can be facilitated by
18 interactive computer-assisted decision-making, especially in
19 situations where decision-relevant data is or can be drawn
20 from multiple heterogenous remote databases.

21
22 Some such possible applications of the invention are to the
23 specification of laboratory tests and also in the veterinary
24 field, and to non-pharmaceutical environments where benefits
25 such as valuable historical records and follow-up studies,
26 as well as quality control improvements, can be obtained

3

3

20 For example, an analogous diagnostic application may provide
21 cost-effective routes to rule in or rule out specific
22 diagnoses. The specificity and sensitivity of individual
23 procedures can be translated into positive predictive values
24 and negative predictive values. By applying decision theory
25 and analyzing probable outcomes of procedures or
26 combinations of procedures in the light of the patient's

1 bio-characteristics and known conditions, diagnostic
2 protocols can be worked up and maintained with current
3 recommendations. Evaluation of the patient's history can
4 enable pretest probabilities to be established and used to
5 modulate the predictive value of one or more tests. Thus
6 the patient's history can drive the selection and
7 establishment of an optimal diagnostic test matrix for
8 identifying a patient's condition or conditions with good
9 specificity and confidence levels.

10
11 Test requirements relating to patient preparations, fasting
12 for example, and sample collection can be system specified.
13 By generating system-maintained identifiers (e.g. bar code
14 labels) for attachment to samples at the point-of-care, a
15 chain of evidence for rigorous sample accessioning can be
16 begun.

17
18 Thus, a range of possible conditions can be evaluated in a
19 differential diagnosis format designed to rule in or rule
20 out a target condition, or conditions, depending upon the
21 results of specified tests.

22
23 Extensions into the veterinary field will be apparent to
24 those skilled in the art in that instead of the physician
25 user referenced herein, reference to a veterinarian is
26 appropriate, and the patient will be an animal such as a pet

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1 dog or cat or valuable livestock, such as a steer or
2 breeding pig or a race horse or breeding stallion.

3
4 Again, although the invention has been described in its
5 preferred embodiments with reference to a physician user it
6 will be apparent that other medical professionals,
7 especially those having prescribing authority, can benefit
8 from applications of it.

9
10 In a more general sense, the invention provides a service
11 professional with significant new benefits, especially
12 during a service encounter with a customer or client, in
13 selecting, specifying or providing technical remedies to
14 consumer problems. For example, in specifying automotive
15 replacement parts a service technician can benefit from an
16 automotive service management system according to the
17 invention in which a database of replacement parts is
18 classified according to the service problem for which the
19 parts might provide a remedy. Thus, for a customer with the
20 problem of brake squeal, the system may provide a list of
21 parts, for example, brake pads, brake pins, brake shims or
22 brake rotors, any of which may provide a remedy to the
23 customers problem of brake squeal. Existing systems permit
24 a service technician, having once identified the type of
25 part they need, to obtain a number or part price and
26 inventory on that part for the customer's specific model of

1 car.

2
3 However, known systems do not permit the professional to
4 query the system by customer problems, nor do they provide a
5 summary of all facets of a solution to a problem leading to
6 a summarized cost of treatment. In addition the inventive
7 system can provide access to technical literature on
8 relevant problems, for example an explanation of the factors
9 causing brake squeal which can be printed out for customers.
10 This is a rather simple example. More complex examples will
11 be apparent to those skilled in the automotive and other
12 arts, especially as this art develops, with sophisticated
13 engine management and other microprocessor controlled
14 systems raising new problems and new technical solutions
15 being required. The inventive system can provide customer
16 problem lists useful for outcome analysis to drive the
17 development of better cars.

18
19 Of great value in the automotive and allied fields, equating
20 a parts supplier, such as a factory or warehouse distributor
21 with a plan benefit company is the ability to provide new
22 product descriptive and price information or updates from
23 multiple sources dynamically, in real time as transactions
24 are created. Noting the desire of a benefits company to
25 apply practical selection guidelines in an unobtrusive
26 manner to the prescribing process, an equivalent technique

1 can be used by car factories to help control warranty
2 service decisions at their dealerships.

3
4 In another embodiment of the invention illustrating its
5 generality, possible insurance vendors and coverage
6 information may be classified according to customer problems
7 so that, for example, an insurance agent may list different
8 vendors and coverage providing specific technical remedies
9 to a customers specific; problem, for example, a recent
10 major automobile collision claim. The relevant novel
11 supportive database could include information
12 differentiating between parties at fault, collision damage,
13 personal injury settlements and so on. In both these
14 examples a problem history related either to the customer or
15 to the customer's automobile can also be created.

16
17 It will be clear to those skilled in the art that use of the
18 prescription management system described herein, employing
19 carefully maintained databases of accurate, reliable
20 prescribing data will produce high quality prescriptions
21 free of many of the problems now plaguing prescription drug
22 use. With confidence that a physician is prescribing
23 appropriate, cost-effective drugs selected from user-
24 personalized lists which link to comprehensive condition and
25 drug lists including the latest available drugs, and that
26 the prescribed drug has been reviewed for contraindications,

1 patients benefit, oversight of the prescribing process by
2 benefit companies and regulatory bodies can be reduced, and
3 litigation resulting from prescribing errors will be
4 reduced. Significant improvements in the quality of care,
5 substantial savings and the elimination of waste can accrue
6 to a national or regional health care system from widespread
7 deployment of the inventive prescription management system
8 described herein.

9
10 Physical embodiment of system software

11 The foregoing specification, read with the accompanying
12 drawings provides an extensive disclosure of, inter alia,
13 various embodiments of systems and software facilitating
14 professionals to select or specify technical products to
15 solve practical problems, and also to create, or assist the
16 professional to create, new products which will assist the
17 professional or their client in achieving desired problem-
18 solving goals.

19
20 It will be understood that the systems and software
21 referenced herein include, either explicitly, or implicitly,
22 software implemented on computers or other appropriate
23 hardware, including user devices such as the personal
24 digital assistants described herein, and such other
25 intelligent data processing devices having a processor, data
26 storage means and the ability to support an operating

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1 system, with or without user interfaces (for example, file
2 servers,), as may be useful in achieving the objectives of
3 this invention.

4
5 Software components and applications embodying the invention
6 can be distributed in electronic bit storage on magnetic,
7 optical, bubble or other media, optionally in transportable
8 form to be interactive with an electronic reading device,
9 for example on computer or optical diskettes, or may be
10 distributed over wired or wireless networks for storage by
11 the recipient on such media.

12
13 Preferred embodiments of the invention provide such media-
14 stored software in a commercial package accompanied by
15 instructions in printed book or booklet form, for deployment
16 of the software on particular embodiments of general purpose
17 computer to cause same to operate as a special purpose
18 computer, in accordance with the objectives of the
19 invention. License agreements, and registration means for
20 updating may also be included. Alternatively, the
21 instructions may also be provided as data files.

22
23 It will further be appreciated that such media-stored
24 software constitutes an electronic customizing machine which
25 can interact with a magnetically or optically cooperative
26 computer-based input device enabling the computer to be

1 customized as a special purpose computer, according to the
2 contents of the software. To cause a computer to operate in
3 such customized, special-purpose mode, the software of the
4 invention can be installed by a user, or other, and will
5 usually interact efficiently with the device on which it is
6 resident to provide the desire special-purpose qualities,
7 only after selection of configuration parameters. When so
8 configured, the special-purpose computer device has enhanced
9 value, especially to the professional users for whom it is
10 intended.

11
12 While some illustrative embodiments of the invention have
13 been described above, it is, of course, understood that
14 various modifications will be apparent to those of ordinary
15 skill in the art. Such modifications are within the spirit
16 and scope of the invention, which is limited and defined
17 only by the appended claims.

18
19 Thus, while certain aspects of the invention have been
20 disclosed as embodied in connection with a prescription
21 management system, it will be apparent that they have
22 broader application in other systems or environments. Some
23 of these aspects are: dynamic assembly of records from
24 source record elements retrieved across a network from
25 heterogenous remote databases; requirements for those
26 elements to be time- and date-stamped for retrospective

1 recreation of records from archival logs; physician-centric
2 drug formularies; data-access control systems and software;
3 the novel directory services described herein and associated
4 online point-to-point e-mail and data retrieval systems;
5 data retrieval networks with API-enabled end-to-end
6 transparency; novel outcome studies, monitoring and alerting
7 procedures, studies and related products; novel scheduled
8 dosage drug packs and dispensing devices, and so on.